Commenters pointed out that, in some jurisdictions, state laws or rules require employers or service agents to provide drug test result information to state law enforcement or safety agencies. To ensure that there is no conflict between Part 40 and these state laws or rules, we have added language (already found in some DOT agency rules) to this section. It says that if requested by a state or local safety agency with regulatory authority over the employer or employee, employers and service agents must provide drug and alcohol test records concerning the employee to the agency. This paragraph also covers Federal agency requests (including requests by DOT, HHS, and the National Transportation Safety Board) for drug and alcohol test records. It should be noted that this paragraph applies only to testing records. It does not authorize provision of specimens.

We have also added a paragraph stating in rule text the advice we have frequently given to employers and service agents faced with subpoenas or other orders directing them, contrary to Part 40 requirements, to produce specimens where Part 40 does not permit. What is a laboratory or other party to do if it gets a request to produce a urine specimen or aliquot for an unauthorized test? The first thing the laboratory should do is to ''just say no,'' giving this DOT regulatory mandate as the reason. If someone seeks a subpoena or other court order directing the production of the specimen, the laboratory's attorneys should seek to quash or resist the action, asserting on the basis of this section that such an order is contrary to Federal law and subject to Federal pre-emption (under the existing pre-emption provisions of DOT agency drug and alcohol regulations). In such cases, we suggest that laboratories call the Department to consult about the matter. If a court ultimately issues a binding order requiring the production of the specimen, the laboratory may comply (we do not seek to make laboratories subject to contempt citations). However, as noted above, employers must continue to implement all consequences of a verified positive test required by DOT rules, regardless of the outcome of the unauthorized test or any personnel process decisions flowing from it.

Section 40.333 What Records Must Employers Keep?

This section is based on § 40.335 of the NPRM. In response to a number of comments and consistent with decisions reflected elsewhere in this document, proposed requirements for the retention of records concerning training of service agents and signed agreements with service agents have been deleted. Under the final rule, collectors, BATs, MROs etc. will maintain their own training records, and employers will not have this responsibility. The requirement to have signed agreements among employers and all service agents has been deleted.

In response to a comment, we have deleted the word ''secure'' from paragraph (c), since we agree that control of access is the key point. One comment suggested that service agents should have up to five business days to get information to employers who are being audited. In our view, each DOT agency's rules and inspection practices should determine how quickly an employer must produce records. The service agent is responsible for meeting the employer's need to comply with DOT agency requirements.

Subpart Q—Roles and Responsibilities of Service Agents

Section 40.341 Must Service Agents Comply With DOT Drug and Alcohol Testing Requirements?

There was only one comment on the proposed § 40.341. AC/TPA wanted C/TPAs to be authorized to act as a DER and to be required to have a certified MRO or administrator in charge. For reasons we have discussed elsewhere, we are not permitting C/TPAs to act as DERs. While we think that training and certification programs for program administrators are a good idea, we do not believe that it is necessary to make them mandatory at this point.

Section 40.343 What Tasks May a Service Agent Perform for An Employer?

This is a new section that makes the basic point that service agents can perform for employers those functions authorized by DOT rules. Proposed § 40.343 dealt with a different issue. DOT has become aware of reports that, particularly in some industries, service agents have imposed requirements on covered entities that exceed the requirements of DOT rules. Some service agents have made compliance with these extra requirements a condition of approval of an employer's DOT drug and alcohol testing program. The proposed section was intended specifically to prevent excesses of this kind.

There were few comments on the proposed section. One said that service agents work for employers in capacities other than compliance with DOT rules. This is doubtless true, but is an issue outside the scope of this rulemaking. One commenter suggested that there was a reverse problem, in that sometimes employers asked service agents (*e.g.*, SAPs) to perform tasks beyond what DOT rules require (*e.g.*, make fitness for duty decisions). We have strengthened language elsewhere in Part 40 to emphasize that it is inappropriate to call on SAPs to make these decisions for employers. A third commenter was concerned that the section might inhibit the ability of service agents to advise employers to recommend provisions not covered by DOT rules. Service agents can recommend provisions not covered by DOT rules, but they cannot make adoption of these recommendations a condition of approving employers' plans for DOT compliance purposes.

The Department has relocated this provision to § 40.355(l).

Section 40.345 In What Circumstances May a C/TPA Act as an Intermediary in the Transmission of Drug and Alcohol Testing Information to Employers?

The proposed § 40.345 made the point that a service agent that did not comply with DOT regulations was subject to PIE proceedings. Comments to this proposal were along the lines of comments on the PIE proposal itself, to which we responded in the ''Principal Policy Issues'' section of the preamble. The substance of this proposed section has been incorporated in § 40.341 of the final rule.

The new § 40.345 incorporates the Department's decision, discussed at length under ''Principal Policy Issues,'' to permit employers to use C/TPAs for a variety of information transmission functions, such as passing drug and alcohol test results from MROs or BATs to employers. We emphasize four points. First, with respect to any and all of the functions that C/TPAs may perform, the employer has the choice of using a C/TPA as an intermediary or getting the information directly from the party (*e.g.*, the MRO) who generates the information. Second, we direct readers' attention to Appendix F. C/TPAs may act as intermediaries *only* with respect to the functions listed in Appendix F.

Third, when C/TPAs act as an intermediary, they must meet all requirements (*e.g.*, concerning confidentiality and timing) that would apply if the party generating the information (*e.g.*, an MRO or collector) sent the information directly to the employer. For example, if a C/TPA transmits the MRO's drug testing results to DERs, it must transmit each drug test result to the DER in compliance with the requirements for MROs set forth in § 40.167. Fourth, as noted in connection with § 40.15, employers remain fully

responsible for receiving all information and taking all actions required under Part 40 and other DOT agency rule.

Section 40.347 What Functions May C/TPAs Perform With Respect to Administering Testing?

One comment on this section suggested that it refer to C/TPAs specifically, rather than service agents generally, because the content of the section covered functions that C/TPAs perform and other service agents (*e.g.*, MROs, laboratories) either should not or typically do not perform. We agree with this comment, and we have changed the language of the section accordingly. Another commenter appeared to be confused about the provision telling service agents not to select employees randomly for testing from a ''follow-up'' pool. This point—which applies to employers as well as C/TPAs—is that follow-up tests are scheduled individually for employees who have returned to safety-sensitive duties after a violation, consistent with the SAP's plan. It is never appropriate to put returned employees into a pool and select them randomly for follow-up testing. Employees never get advance notice of the time of a follow-up test, but follow-up testing is in no way random. On the other hand, in addition to being subject to follow-up testing, returned employees must be in the regular random testing pool, and are subject to selection for random testing on the same basis as all other covered employees.

Section 40.349 What Records May a Service Agent Receive and Maintain?

Some commenters on this section were concerned that because the proposed rule used the general term ''service agent'' in this section, the section glossed over restrictions on the activities of MROs and laboratories. They suggested that, as in the case of § 40.347, we limit the section to C/TPAs. While we agree that C/TPAs perform many record management functions, it does not appear to us that the provisions of this section apply only to C/TPAs. However, in response to the commenters' concerns, we are prefacing this section with an ''except where otherwise specified in this part'' statement (we did the same in § 40.347). The import of this language is that, where MRO, laboratory, or other provisions of the rule impose requirements or restrictions beyond those of this section, those requirements or restrictions control.

Another comment suggested clarifying that DOT access to service agent records and facilities does not apply to records and facilities not involved in the DOT drug and alcohol testing program. This point seems clear on the face of the proposed and final provisions, so we will not restate the obvious. Another comment objected to requiring this access, and asked for a justification. This is equally obvious: in order to maintain proper oversight of an important safety program, the Department needs access to the records and facilities of those who actually perform program tasks.

Section 40.351 What Confidentiality Requirements Apply to Service Agents?

This section is also based on parts of proposed § 40.349. A number of comments pertained to proposed § 40.349(e), relating to handling of the CCF. There is no equivalent to this proposed paragraph in the final rule. A few comments also supported allowing ''blanket'' releases of information. As under the present rule, we believe that blanket releases compromise the confidentiality of employee-specific records and are subject to abuse. The final rule continues this prohibition.

§ 40.353 What Principles Govern the Interaction Between MROs and Other Service Agents?

This section is based on § 40.351 of the NPRM. Much of the comment concerned the discretion of C/TPAs, acting as an intermediary, to transmit laboratory results to MRO and MRO verification decisions to the employer. As discussed in ''Principal Policy Issues'' and in connection with § 40.345, the final rule permits the latter and prohibits the former.

Some commenters appeared to believe that the proposed section required MROs to exercise full-time, in-person, over-the-shoulder supervision of their staffs. This is not the case. As long as MROs really supervise their staff, this supervision need not always take place at the same site. We are aware that MRO operations may have more than one site and that an MRO cannot be everywhere at once. On the other hand, the rule is intended to prohibit C/TPA staff, working on their own or under C/TPA rather than MRO supervision, from performing MRO staff functions.

To reduce paperwork, we have deleted a proposed requirement for written agreements between MROs and other service agents.

§ 40.355 What Limitations Apply to the Activities of Service Agents?

Some commenters on this section favored allowing C/TPAs to act as DERs and to act as an intermediary in transmitting results from laboratories to MROs. Another commenter opposed any ''firewalls'' between C/TPAs and MROs. As we have explained above, the final rule does not permit C/TPAs to act as DERs or to transmit laboratory results to MROs. In our view, some firewalls between MROs and other participants in the testing process are essential to maintaining the necessary independence of MROs.

Another commenter said that employers, not SAPs, should make follow-up testing determinations. SAPs are used in the return-to-duty process because of their expertise in evaluating individuals with drug and alcohol problems. We believe that their expertise should be used to determine follow-up testing requirements. Employers may know their workers, of course, but they are not typically experts in drug and alcohol abuse evaluation and treatment.

One commenter suggested adding a sentence specifying that MROs could determine that an individual had refused a test, in the context of an adulteration or substitution finding. We agree, and we have added this language.

We have added a paragraph concerning a problem that the Department has occasionally encountered. It states that service agents must not intentionally delay the transmission of drug or alcohol testing-related documents because of a payment dispute or other reasons. Parties can work out disputes among themselves, but it is essential to the safety purposes of this program that drug and alcohol testing results and other information flow freely. As a safety matter, this information must not be held hostage to business disagreements.

Subpart R—Public Interest Exclusions

The Department discussed PIEs extensively in the ''Principal Policy Issues'' portion of the preamble. We will not repeat this discussion here, focusing instead on points in the individual sections of Subpart R that should be highlighted.

§ 40.361 What Is The Purpose of a Public Interest Exclusion (PIE)?

Section 40.363 On What Basis May the Department Issue a PIE?

Section 40.365 What Is the Department's Policy Concerning Starting a PIE Proceeding?

These sections emphasize that the basic purpose of PIEs is to protect the public from serious noncompliance on the part of service agents. PIEs are not an exclusive remedy: We can take other actions (*e.g.*, sanctions against employers, referral to the DOT Inspector

General) if circumstances warrant. The basic grounds for issuing a PIE are serious noncompliance with Part 40 or DOT agency drug and alcohol testing regulations and failure to cooperate with DOT oversight and enforcement efforts.

Section 40.365 includes a list illustrating the kinds of misconduct that we believe warrant initiating a PIE proceeding. We emphasize that this is not an exhaustive or exclusive list. We can and will initiate PIEs on the basis of other fact situations, if warranted. However, this list should give interested persons a good idea of the Department's policy concerning the level of seriousness that we intend to be the basis for PIE actions. The items on the list all concern such matters as safety, the outcomes of test results, privacy and confidentiality, due process and fairness for employees, the honesty and integrity of the testing program, and cooperation with or provision of information to DOT agency representatives. Many of the items are drawn from problems the Department has noted under the existing Part 40.

We note that the PIE provisions of the rule are not intended to have retroactive effect. That is, the Department would not initiate a PIE proceeding on the basis of conduct that occurred before the PIE provisions took effect.

Section 40.367 Who Initiates a PIE Proceeding?

Section 40.369 What Is the Discretion of an Initiating Official in Starting a PIE Proceeding?

Section 40.371 On What Information Does an Initiating Official Rely in Deciding Whether To Start a PIE Proceeding?

Section 40.411 What Is the Role of the DOT Inspector General's Office?

These sections concern the Department's decision about whether to begin a PIE proceeding. Only selected DOT officials are authorized to begin such a proceeding: DOT agency drug and alcohol program managers, an official of ODAPC other than the Director (who, as the decisionmaker, is precluded from any role in initiating or prosecuting a PIE proceeding), or the designee of these officials. We emphasize that individual inspectors and subordinate staff members, while they may provide information to initiating officials, are not themselves authorized to initiate PIE proceedings.

Initiating officials have broad discretion in deciding whether to start a PIE proceeding, though this discretion must be exercised with the policy expressed § 40.365 in mind. DOT is never required to start a PIE proceeding. An initiating official can take into account such factors as his or her judgment of the seriousness of the matter and the availability of resources to investigate and prosecute a matter adequately.

An initiating official can rely on credible information from any source in deciding whether to start a proceeding. As many commenters requested, the initiating official will make an informal contact with the service agent before sending a correction notice, in an attempt to determine if the service agent has any information that would help the initiating official make his or her decision to initiate a proceeding.

While the DOT inspector general (IG) is not an initiating official in the PIE process, the IG can investigate complaints concerning waste, fraud, and abuse in the drug and alcohol testing program. The initiating official can use information from IG investigations and audits as the basis to begin a PIE proceeding. The IG can also take action leading to criminal or civil action against a service agent or employer if the facts warrant.

Section 40.373 Before Starting a PIE Proceeding, Does the Initiating Official Give the Service Agent an Opportunity To Correct Problems?

Section 40.375 How Does the Initiating Official Start a PIE Proceeding?

These sections describe the first formal steps in any PIE proceeding. Before taking other action, the initiating official sends a correction notice, outlining the compliance problem and giving the service agent 60 days to correct it. If the service agent documents correction of the problem in this period, the official does not pursue a PIE proceeding. If not, the official sends a notice of proposed exclusion (NOPE) to the service agent, detailing the basis for the proposed exclusion and informing the service agent of the next procedural steps.

There may be some problems that cannot be corrected, or some misconduct so serious that subsequent corrective steps are insufficient to make up for the effects of noncompliance. For example, an MRO who has counterfeit medical credentials probably cannot correct this problem. A laboratory that has demonstrated a significant lack of business integrity by falsifying evidence or a pattern or practice of careless conduct resulting in the cancellation of numerous tests might have great difficulty demonstrating that it has made adequate changes to make up for the problems it caused. The Department is not limited, in deciding whether to initiate a PIE proceeding, to purely prospective considerations (*e.g.,* analogous to the ''imminent [future] harm'' standard HHS uses in deciding to take certification action against a laboratory). Nor is the Department required to accept, on face value, assurances from a service agent that it has learned its lesson and will comply in the future. The Department will make judgments of this kind on a case-by-case basis.

Section 40.377 Who Decides Whether To Issue a PIE?

This sections focuses on the role of the ODAPC Director as decisionmaker. Section 40.377 articulates the firewall between the Director and the initiating official, to ensure impartiality. The Director can delegate the decisionmaking role to another official (*e.g.,* in a case where the Director would be unavailable to decide the case or recused himself or herself because of a potential conflict of interest), who would then be subject to the same firewall requirements.

Section 40.379 How Do You Contest the Issuance of a PIE?

Section 40.381 What Information Do You Present to Contest the Proposed Issuance of a PIE?

Section 40.383 What Procedures Apply if You Contest the Issuance of a PIE?

Section 40.385 Who Bears the Burden of Proof in a PIE Proceeding?

These sections cover an important part of the administrative due process protections built into the PIE provisions of the rule. Within 30 days of getting a NOPE, a service agent must contact the Director and make arrangements to present information and arguments. If the service agent asks to meet with the Director, the Director will schedule a meeting. At this meeting, or in a written presentation, the service agent may provide any arguments or factual information it believes relevant to the proposed issuance of a PIE, its scope and duration. We emphasize that the opportunity to meet with the Director is not a ''hearing'' or ''trial,'' with formal rules of evidence. The Director will consider any relevant evidence and listen to any witnesses the initiating official or the service agent presents. Because the initiating official is the proponent of the PIE action, he or she bears the burden of proof (by a preponderance of the evidence) on all issues. To justify issuing a PIE, the Director must find that the service agent failed or refused to perform drug and/or alcohol testing services as required by this part or is in serious noncompliance

with a DOT agency drug and alcohol regulation.

Section 40.387 What Matters Does the Director Decide Concerning a Proposed PIE?

Section 40.389 What Factors May the Director Consider?

Section 40.391 What Is the Scope of a PIE?

Section 40.393 How Long Does a PIE Stay in Effect?

Section 40.407 May a Service Agent Ask To Have a PIE Reduced or Terminated?

These sections concern what decisions the Director makes and which factors the Director considers in deciding on whether to issue a PIE, as well as the scope and duration of a PIE. When the Director receives the NOPE and the service agent's response to it, the Director can dismiss the proceeding (*e.g.,* for not raising a sufficiently serious noncompliance issue to warrant issuing a PIE), remand it to the initiating official for more fact finding, or continue with the proceeding. Whenever a proceeding does go to decision, the Director would make determinations concerning disputed factual issues, whether the facts support issuing a PIE, and the scope and duration of a PIE. The factors the Director considers in making these decisions include the seriousness of the noncompliance, the pervasiveness of the noncompliance within the service agent's organization, and the compliance disposition of the service agent.

The scope of a PIE was the subject of many comments. In the final rule, the initiating official proposes a scope for the PIE, the service agent can contest the proposal, and the Director decides what the scope should be. The general rule is that a PIE applies to parts of an organization or types of services that are affected by the service agent's noncompliance. The more pervasive the misconduct, the broader the scope of the PIE. The rule text provides several examples of the Department's thinking on how to view the proper scope of a PIE.

There are also situations in which the PIE can apply to individual officers or employees of the service agent, if they are responsible for the noncompliance that formed the basis for the PIE. This provision is intended to prevent individuals from going into business under a different business or corporate name while a PIE remains in effect against the service agent they worked for. The same is true of businesses affiliated with the service agent concerning which the Department issued a PIE.

A PIE stays in effect from one to five years. Like the scope of a PIE, the duration of a PIE is proposed by the initiating official, may be contested by the service agent, and is decided upon by the ODAPC Director. The Director's decision is based on such factors as the seriousness of the noncompliance on which the PIE is based and the continued need to protect employers and employees from the service agent's noncompliance. The Director considers factors such as those listed in § 40.387 in making this decision.

After a PIE has been in effect for nine months, the service agent can apply to have its duration shortened. If the Director verifies that the sources of noncompliance have been eliminated and that all drug or alcohol testing-related services the service agent would provide to DOT-regulated employers will be consistent with the requirements of this part, the Director may issue a notice terminating or reducing the PIE. We emphasize that this process is limited to the issues of duration and scope: it is not an appeal or reconsideration of the decision to issue the PIE.

Section 40.395 Can You Settle a PIE Proceeding?

Section 40.397 When Does the Director Make a PIE Decision?

Section 40.399 How Does the Department Notify Service Agents of Its Decision?

Section 40.401 How Does the Department Notify Employers and the Public About a PIE?

Section 40.403 Must a Service Agent Notify Its Clients When the Department Issues a PIE?

Section 40.405 May the Federal Courts Review PIE Decisions?

Section 40.413 How Are Notices Sent to Service Agents?

The next group of provisions concern the mechanics of making PIE decisions and informing people about them. The initiating official and the service agent can settle a PIE proceeding at any time before the Director issues a decision. The Director must concur in the settlement, which could include, for example, provisions to ensure compliance or a period of voluntary exclusion during which the service agent agrees not to provide certain services to DOT-regulated employers while it fixes noncompliance problems.

The Director is normally responsible for making a decision within 60 days of the record of the proceeding being completed. The Director can extend this normal decision period for 30 days at a time for good cause. It is the Department's policy to expedite these important decisions, however. Once the Director issues a decision, it is a final administrative action of the Department, subject, like all such actions, to judicial review under the Administrative Procedure Act.

The Director must provide written notice of a PIE to the service agent, including a statement of the basis for his or her decision and the scope and duration of the PIE. The Department also informs the public about the PIE though a web site posting and a **Federal Register** notice. We also anticipate informing employer and testing industry groups about the action, so that they can inform their members. The service agent also has an affirmative responsibility to inform customers about the PIE, so that they can obtain services from and transfer records to other service agents. Finally, § 40.113 concerns the mechanics of how notices are sent to service agents and when they are deemed to have been received. As a policy matter, the initiating official will make reasonable efforts to follow up with the service agent to ensure that the service agent has received and understood the notice.

Section 40.409 What Does the Issuance of a PIE Mean to Transportation Employers?

Employers have an affirmative responsibility to stop using the services of a service agent that is subject to a PIE. This obligation begins 90 days *after* the Director issues the PIE, to give the employer time to find another service provider. The obligation applies to services provided through an affiliate of the service agent subject to the PIE as well as the service agent itself, and it applies to employers in all DOT-regulated industries. It is important to note that a PIE does not invalidate otherwise proper drug and alcohol tests in which the service agent was involved before, and for 90 days after, the issuance of the PIE. The rule text spells out the operation of this provision in more detail.

Appendices

Appendix A

During the last decade of drug testing, the Department has not regulated nor standardized the materials (*i.e.,* collection containers, specimen bottles, etc.) used in DOT-mandated drug

testing. During the first few years of drug testing, only one specimen bottle was required. Subsequent to the Omnibus Act, split specimen collections became a requirement for four of the six DOT agencies. In general, each laboratory provided to the collection site or the employer laboratory specific collection kits, many of which differed in composition.

The introduction of the split, the fact that in the pipeline and maritime industry split collection was an employer option, and the wide variance among the laboratories' kits, resulted in significant problems and numerous tests had to be cancelled based on collector error that, at times, was due to the differences in the makeup of the kits.

Several years ago, the Department requested all laboratories to provide samples of their urine collection kits. These were reviewed against the then current regulatory requirements (*e.g.,* tamper-evident seals on the bottles, availability and use of shipping container seals, collection instructions), and a majority of kits did not meet the regulatory requirements. Laboratories were notified and corrective action was recommended, but the Department did not take any specific action to standardize these kits at that time.

The Department is convinced that the new requirement for all DOT agencies to use splits, and the development of a standard kit, will result in fewer mistakes and cancellations of drug tests. In that light, Appendix A spells out broad criteria for the composition of urine collection kits.

The requirement for a collection container should minimize the need to give the employee both bottles, when there is no collection container in the kit, and request the employee to urinate into only one bottle. In some cases, employees fill both bottles and collectors submit these, resulting in splits that do not reconfirm. In some cases, the two bottles contained urine of different colors, but collectors submitted them anyway.

The requirement that the collection container and the bottles be wrapped or sealed in a plastic bag was established earlier to prevent accusations by the employee that either the collector or someone at the collection site introduced some foreign substance into the containers, causing a positive result. The standards specifically spell out that the collection container needs to be securely wrapped separately from the specimen bottles and that the bottles must be either shrink wrapped or sealed in plastic bags or may be secured with other methodology provided that the tamper-evident mechanism is effective and easily discernable to the employee.

For example, the use of a tiny filament between the bottle and the cap which breaks when the bottle is first opened may be effective in determining if the bottle was opened, but only if the employee has this pointed out to him or her. Even at that, the employee would have to look very closely to see if the filament is or is not attached. Most collectors will not spend the time to go through this process and employees can say they were not really able to tell if the filament was in place. It is much easier to defend and remember that a bottle was wrapped in a plastic bag, rather than argue that the employee was or was not specifically shown the filament or that he or she actually did or did not see the filament. Conversely, a bottle that has a paper label.

The use of a leak-resistant plastic bag has been in place for a number of years, driven primarily by U.S. Postal Service and courier and shipping services requirements as a safety issue related to transportation of biological specimens. Under the new standards, the plastic bags must not only be leak-resistant (no zip locked bags), but must also be tamper-evident. In other words, once the bag is sealed it cannot be opened without the opening becoming obvious.

Under current rules, there is a requirement that the shipping container be sealed with a shipping container seal that is initialed or signed and dated by the collector. In the NPRM, we proposed to use a tamper-evident seal on the plastic bag instead of the shipping container, since in many cases, collectors may collect several specimens in plastic bags and hold or store them until they have several which can then be placed into a shipping contained which is subsequently sealed. There were few comments related to the kit, but laboratories did indicate that when a shipping container, usually a box, arrives at the laboratory with a broken seal, the specimens are tested provided the specimen bottle seals are intact. To date, the Department is not aware of any problems related to this practice. However, it does call into question the purpose of the second (shipping container) seal. The Department's position is that if the leak-resistant plastic bag is tamper-evident, that serves as the secondary protection, which is currently ensured by the shipping seal.

The primary concern is, and always has been, the integrity of the specimen bottle seals. As long as the integrity of the specimen bottle seals is intact, the condition of the shipping container seal is not relevant. The standards listed in Appendix A, therefore, do not include a requirement for a shipping container or plastic bag seal.

The current regulatory requirement is that the ''specimens shall be placed in shipping containers designed to minimize the possibility of damage during shipment (*e.g.,* specimen boxes and/or padded mailers)''. In many cases, kits contain cardboard boxes designed to hold only two bottles for shipment. In some cases, collection sites may, and do, place a number of specimens in plastic bags and then into one large shipping container or box, and transport the specimens in that manner. With the advent of stronger plastics, some laboratories are requesting collection sites to transport bottles wrapped in leak-resistant plastic bags which are placed into larger plastic envelopes, contending that because the specimen bottles are constructed of stronger plastic, this is an acceptable practice.

The Department has discussed this issue of transporting specimens with two of the largest courier services and both have expressed their concerns about leakage of urine specimens in transit and concern for the safety of their employees. Both courier services require a watertight primary receptacle (bottle) and a secondary watertight container, which in this case would be the leak-resistant plastic bag. One courier requires a sturdy outer package consisting of corrugated fiberboard, wood, metal, or rigid plastic; Styrofoam boxes, plastic bags, and paper envelopes are not acceptable as outer packaging. The second major courier requires that the primary container (bottle) meet a 150-pound crush test. If it meets that test, it may be placed in a leak-resistant plastic bag or container and then may be placed in a secondary leak-resistant plastic envelope without further packaging. Conversely, if the bottle(s) does not meet the crush test, it must be placed into a secondary package, which meets the 150-pound crush test. The secondary package may then be placed into a plastic shipping envelope.

The Department has determined that current shipping regulations and requirements are sufficient to ensure that specimens are shipped in a manner that will protect them from damage. Therefore, the standards direct that the specimen bottles be shipped in containers that can sufficiently protect them from damage; the standards do not specify the type of material or the extent of weight (crush test) that the shipping containers should meet. The standards also permit the specimens to be transported to a laboratory in the leak-resistant plastic bag provided they are hand-carried by a laboratory courier. In other words, the courier picks the

specimens up in whatever is a convenient shipping or carrying container and does not subsequently place them into a system (automated transportation, another delivery courier, or on a plane, railroad, or truck), but personally delivers them to the laboratory.

Appendix B

Appendix B is simply a list of the data elements and format for the semi-annual laboratory report provided to employers. Laboratories should follow this format when they compose these reports.

Appendix D

This appendix identifies the format and type of information that the MRO needs to submit to DOT when a split specimen test fails to reconfirm the presence of the drug/drug metabolite, adulterant, or the substitution finding found in the primary specimen.

There has been a long-standing practice under the current rule that when the employee requests a test of the split specimen and the test of the split fails to reconfirm the presence of the drug/drug metabolite that was found in the primary specimen, or if the split was not available (*i.e.,* not collected or leaked in transit), the MRO was required to report this result to the Department. The purpose of this report was to determine if this was an administrative or collection error (*e.g.,* the primary bottle and the split bottle were not the same urine) or if the failure to reconfirm was one of a technical nature, requiring review by HHS. Although the majority of ''failures to reconfirm'' have been due to the unavailability of the split specimen, some of the technical problems led to the discovery of the various adulterants that are currently used to circumvent the testing process. Based on this, the Department will continue to require this reporting by the MRO.

The Department has also decided to permit an employee to request the test of the split specimen when the primary specimen is reported as adulterated or substituted. Based on that decision, we have determined that should the split fail to indicate the adulterant or the substitution is not supported by the test of the split or the MRO cancels the test based on medical evidence, the MRO needs to report this cancellation to the Department in the same manner as if it was a positive result which failed to reconfirm.

There is not a standard ''report'' that the MRO needs to fill out. However, for consistency of information, Appendix D provides the format for the information that the Department needs to fully assess if there are any technical problems in the testing process. For ease of use, the same format can be used for reporting cancellation of a positive as well as for adulteration and substitution.

Appendix E

This Appendix lists the 12 criteria the Department examines in determining whether certification organizations should be accepted under §§ 40.281–40.283 for participation in the SAP program. The first eleven items are the same criteria the Department has used in evaluating other certification organizations that are already part of the program (*e.g.,* ICRC). The twelfth item is NCCA accreditation, discussed in the preamble to § 40.281.

Appendix F

This Appendix is a list of the drug and alcohol testing information transmission functions that C/TPAs are authorized to perform (see § 40.345) C/TPAs may, acting as an intermediary, transmit the information in the listed regulatory sections to the DER for an employer, if the employer chooses to have the C/TPA do so. These are the only items that C/TPAs are permitted to transmit to the employer as an intermediary. The use of service agent intermediaries is prohibited in all other cases, such as transmission of laboratory drug test results to MROs, the transmission of SAP reports to employers, and the transmission of positive alcohol test results.

In every case, the C/TPA must ensure that, in transmitting the information, it meets all requirements (*e.g.,* concerning confidentiality and timing) that would apply if the party originating the information (*e.g.,* an MRO or collector) sent the information directly to the employer. For example, if a C/TPA transmits MROs' drug testing results to DERs, you must transmit each drug test result to the DER in compliance with the requirements for MROs set forth in § 40.157.

Appendix G

The ATF included in Appendix G is a slight modification of the existing alcohol testing form. One commenter suggested that a new alcohol testing form be developed that incorporated requirements proposed by the NPRM (*e.g.,* the name of the DER, whether an STT used a saliva device). We believe that a revised form will serve the program better by allowing us to capture the necessary information. At the same time, it will no longer require the employee to sign in Step 4 if the alcohol concentration is less than 0.02. This signature will only be necessary if the alcohol concentration is 0.02 or higher on the confirmation test. Consistent with the CCF, all pages of the form may be white, with the distribution legend at the bottom of pages 2 and 3 following the colors of the current form. The OMB control number of the new form will be OMB 2105–0529, the same as for the current form. Program participants may start using the form January 18, 2001. Use of the form will become mandatory on August 1, 2001.

Regulatory Analyses and Notices

Executive Order 12866 and DOT Regulatory Policies and Procedures

This rule is a significant rule for purposes of Executive Order 12866. It is significant because of its policy importance and its impact upon sizeable industries. It is not, however, an economically significant regulation. It is a reworking of existing requirements, imposing few new mandates, and should not have significant incremental costs. Because of its multimodal impact and policy interest to regulated parties and service agents, it is a significant rule for purposes of the DOT Regulatory Policies and Procedures. Throughout this regulation, we have attempted to balance the costs of new requirements with the cost savings accrued through the elimination of some current requirements.

Economic Impacts

There are two features of the regulation that would add new requirements having economic impacts. The first is the requirement for validity testing. As the result of work by HHS and the laboratories, these protocols are already in place and are being used by most laboratories, so we expect the incremental costs of this requirement to be modest. The Department believes that public safety is well-served by these steps to identify and hold accountable employees in safety-sensitive positions who attempt to tamper with the testing process.

Second, the rule includes additional training requirements for some service agents. Errors in the testing process resulting from lack of training can lead to increased employer program costs and increased paperwork required to document the errors and repeat the testing process. The rule upgrades requirements for collectors, MROs, and SAPs. Well-attended training courses for MROs already exist, as do some collector and SAP courses.

At the same time, the Department anticipates cost savings from some provisions of the regulation, such as the

reductions in blind specimen requirements and mitigation of some reporting requirements. The additional training requirements discussed in the previous paragraphs will help to reduce costs from errors in the system. For example, every time a better-trained collector conducts a collection properly instead of making a mistake, the costs of developing memorandums for correction, preparing laboratory litigation packages, arbitration or court proceedings, and reversing personnel actions are avoided.

The Department has estimated cost increases and decreases that could be expected if the proposed rule's provisions are made final. It is important to understand that this is a big program, touching some 8.34 million employees working for about 673,413 employers. Around 30,000 individuals and organizations work as service agents.

In terms of new costs, the Department estimates an annual cost of about $1.4 million for validity testing. With respect to training for SAPs. MROs, BATs, STTs, and collectors, we anticipate that annual costs will run about $4 million. In addition, we estimate that there will be one-time costs for a variety of administrative requirements in the first year of implementation of approximately $1.93 million.

On the other hand, we anticipate saving at least $4.3 million per year from the reduction in blind specimen testing (the savings will probably be somewhat greater, because fewer organizations will be required to submit blind specimens). By changing the current quarterly laboratory report requirement to require a semiannual report, we anticipate saving another $2.5 million annually. By permitting positive, adulterated, and substituted test results to be faxed rather than sent by overnight express, we project an annual $3.3 million saving. These annual savings are greater than the additional annual costs we anticipate for the proposed rule. In total, then, we estimate that the new rule will result in about $7.4 million in incremental costs versus $10.1 million in incremental savings, compared to the existing rule.

The Department has placed in the docket for this rulemaking a document describing the basis for these estimates in greater detail.

Executive Order 13132 and Federalism

This final rule does not have sufficient Federalism impacts to warrant further action under Executive Order 13132. The Department notes that the provisions of Part 40 are incorporated by reference in the other DOT agency drug and alcohol testing regulations, which have existing pre-emption provisions in them. Consequently, for example, a provision of a state or local law or regulation that conflicted with a provision of Part 40 could be subject to pre-emption on the basis of this existing operating administration authority.

Regulatory Flexibility Act

With respect to the Regulatory Flexibility Act, the Department certifies that this rule does not have a significant economic impact on a substantial number of small entities, so a Regulatory Flexibility analysis has not been prepared. It is clear that the rule affects large numbers of small entities. Many thousands of covered employers are small businesses (*e.g.,* small trucking companies, small transit authorities), as are many service agents (*e.g.,* occupational health clinics). Given the small, and overall favorable, net change in regulatory costs compared to the present rule, spread over these thousands of small entitites, the cost impact per entity is expected to be negligible.

We have also taken some steps, such as the reduction in blind specimens, the reduced frequency of some reports, and the discretion we have given C/TPAs to act as intermediaries in some situations, that should assist small entities in complying and reduce their burdens. For the smallest entities (*e.g.,* owner-operators), we have also permitted C/TPAs to perform some additional functions. The PIE provision should reduce costs to small employers as the result of noncompliance by service agents. Our ability to create special provisions for small entities is limited by the need to have uniform requirements to ensure safety and fairness to employees. There must be a single standard for the accuracy and integrity of the program and the protection of legitimate employee interests that cannot vary with the size of the employer or service agent.

This rulemaking resulted from a ''610 Review'' under the Regulatory Flexibility Act. We have reviewed the existing program to identify areas in which the rule can be improved with the effect of assisting small businesses to comply in a rational and cost-effective manner. In addition to the general clarification of the program this rule provides, we have identified some specific areas (*e.g.,* blind specimen requirements, the addition of the public interest exclusion provision, the reduction in reporting frequencies, the discretionary use of C/TPAs to transmit information) that should be particularly helpful to small regulated employers.

Paperwork Reduction Act

Since the inception of the Department's drug and alcohol testing program, each individual DOT agency has complied with the requirements of the Paperwork Reduction Act (PRA) by submitting a justification to the Office of Management and Budget (OMB). These PRA submissions reflected requirements derived from the respective DOT agency drug and alcohol regulations as well as from Part 40. The submissions were never presented to OMB in a coordinated fashion, nor were they reviewed together to ensure that all drug and alcohol program requirements were reflected in a manner that was consistent, accurate, and non-duplicative.

In January 2000, the Department began an effort to evaluate prior PRA submissions in an attempt to address disparities between DOT agency estimates as well as the aggregate burden and cost estimates. A One-DOT group was formed. Its goals were to bring consistency and simplicity to DOT's PRA submissions; eliminate PRA submission duplication between and among DOT agencies, OST, and other Federal agencies; eliminate PRA submission discrepancies; and, more importantly perhaps, ensure accuracy of submissions. In addition, the group decided to standardize cost, hour, and wage indicators, where possible, and to identify task commonalities in DOT agency regulations and standardize how they are reported to OMB. The group sought to determine where program PRA responsibilities for specific drug and alcohol program elements lie—with the DOT agencies, OST, or other Federal agencies.

The group identified a total of 37 PRA tasks contained in one or more of the regulations of six DOT agencies (*i.e.,* that properly reside in the operating administration rules rather than in Part 40). Some tasks were shared by all or some DOT agencies, while other tasks were peculiar to only one DOT agency. The operating administrations subsequently made PRA submissions to OMB for these items, which OMB approved. These submissions resulted in a reduction in the paperwork burden attributable to operating administration rules, both because Part 40-related burdens were kept separate and because a significant overestimate of the burden connected with one of the operating administration programs was corrected. The total reduction was over 50 million hours.

Next, the Department constructed a baseline for the information collection burden attributable to the existing Part

40 (most of which had not previously been accounted for in PRA submissions or had been subsumed under operating administration submissions). This baseline is approximately 2.23 million hours. The Department submitted a PRA request to OMB concerning this material, which OMB has approved.

Third, the Department compared the information collection burden of the existing Part 40 baseline to the estimated burden for the new Part 40. Comparing the existing rule to the new rule, there are some items that increase (*e.g.,* obtaining test results from previous employers, MRO review of negative test documentation, employer SAP lists being provided to employees), in part because they previously were accounted for under operating administration rules. Other items decreased (*e.g.,* changing from quarterly to semi-annual laboratory reports). The largest decrease resulted from the drug testing form's burden hours being accounted for under the PRA responsibility of HHS. Cumulatively, the new Part 40's information collection burden is approximately about 842 thousand hours, or about 1.39 million hours less than that of the existing Part 40.

For informational purposes, the Department has placed its entire Paperwork Reduction Act package on the internet, on the same Docket Management System web site on which comments on this rulemaking are posted. Interested persons may review this material electronically. The following web address provides instructions and access to the DOT electronic docket: *http://dms.dot.gov/search/.* To find the material on the Part 40 rulemaking, just enter the number 6578 in the ''docket number'' search dialog box.

In addition, we note that § 40.25, which requires employers to obtain information from applicants about previous drug and alcohol test results, was not previously the subject of PRA-related comment. While this section is part of the PRA package OMB has approved in connection with Part 40, you may comment about the information collection aspects of the section. Please send any comments to Jim L. Swart, Drug and Alcohol Policy Advisor, Office of Drug and Alcohol Policy and Compliance (ODAPC), 400 7th Street, SW., Room 10403, Washington, DC 20590, 202–366–3784 (voice), 202–366–3897 (fax), or *jim.swart@ost.dot.gov* (e-mail).

Other Executive Orders

There are a number of other Executive Orders that can affect rulemakings. These include Executive Orders 13084 (Consultation and Coordination with Indian Tribal Governments), 12988 (Civil Justice Reform), 12875 (Enhancing the Intergovernmental Partnership), 12630 (Governmental Actions and Interference with Constitutionally Protected Property Rights), 12898 (Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations), 13045 (Protection of Children from Environmental Health Risks and Safety Risks), and 12889 (Implementation of North American Free Trade Agreement). We have considered these Executive Orders in the context of this rule, and we believe that the rule does not directly affect the matters that the Executive Orders cover. We have prepared this rulemaking in accordance with the Presidential Directive on Plain Language.

List of Subjects in 49 CFR Part 40

Administrative practice and procedures, Alcohol abuse, Alcohol testing, Drug abuse, Drug testing, Laboratories, Reporting and recordkeeping requirements, Safety, Transportation.

Issued this 1st day of December 2000, at Washington, DC.

Rodney E. Slater,

Secretary of Transportation.

For the reasons set forth in the preamble, the Department of Transportation amends 49 CFR subtitle A as follows:

1. Effective January 18, 2001, amend the current 49 CFR part 40 as follows:

PART 40—[AMENDED]

a. The authority citation for Part 40 is revised to read as follows:

Authority: 49 U.S.C. 102, 301, 322, 5331, 20140, 31306, and 45101 *et seq.*

b. Add Subparts E and F to read as follows:

Subpart E—Additional Administrative Provisions and Validity Testing

Sec.

Subpart F—Public Interest Exclusions

Subpart E—Additional Administrative Provisions and Validity Testing

§ 40.201 Additional definitions.

The following definitions apply to the provisions of this subpart E and subpart F of this part:

Adulterated specimen. A specimen that contains a substance that is not expected to be present in human urine, or contains a substance expected to be present but is at a concentration so high that it is not consistent with human urine.

Affiliate. Persons are affiliates of one another if, directly or indirectly, one controls or has the power to control the other, or a third party controls or has the power to control both. Indicators of control include, but are not limited to: interlocking management or ownership; shared interest among family members; shared facilities or equipment; or common use of employees. Following the issuance of a public interest exclusion, an organization having the same or similar management, ownership, or principal employees as the service agent concerning whom a public interest exclusion is in effect is regarded as an affiliate. This definition is used in connection with the public interest exclusion procedures of Subpart F of this part.

Confirmation (or confirmatory) validity test. A second test performed on a urine specimen to further support a validity test result.

Dilute specimen. A specimen with creatinine and specific gravity values that are lower than expected for human urine.

Initial validity test. The first test used to determine if a specimen is adulterated, diluted, or substituted.

Office of Drug and Alcohol Policy and Compliance (ODAPC). The office in the Office of the Secretary, DOT, that is responsible for coordinating drug and alcohol testing program matters within the Department and providing information concerning the implementation of this part.

Split specimen. In drug testing, a part of the urine specimen that is sent to a first laboratory and retained unopened, and which is transported to a second laboratory in the event that the employee requests that it be tested following a verified positive test of the primary specimen or a verified adulterated or substituted test result.

Substituted specimen. A specimen with creatinine and specific gravity values that are so diminished that they are not consistent with human urine.

§ 40.203 Who issues authoritative interpretations of this regulation?

ODAPC and the DOT Office of General Counsel (OGC) provide written interpretations of the provisions of this part. These written DOT interpretations are the only official and authoritative interpretations concerning the provisions of this part. DOT agencies may incorporate ODAPC/OGC interpretations in written guidance they issue concerning drug and alcohol testing matters.

§ 40.205 What is validity testing, and are laboratories authorized to conduct it?

(a) Specimen validity testing is the evaluation of the specimen to determine if it is consistent with normal human urine. The purpose of validity testing is to determine whether certain adulterants or foreign substances were added to the urine, if the urine was diluted, or if the specimen was substituted.

(b) As a laboratory, you are authorized to conduct validity testing.

§ 40.207 What validity tests must laboratories conduct on primary specimens?

As a laboratory, if you conduct validity testing under the authorization of § 40.205(b), you must conduct it in accordance with the requirements of this section.

(a) You must test each primary specimen for creatinine. You must also determine its specific gravity if you find that the creatinine concentration is less than 20 mg/dL.

(b) You must measure the pH of each primary specimen.

(c) You must test each primary specimen to determine if it contains substances that may be used to adulterate the specimen. Your tests must have the capability of determining whether any substance identified in current HHS requirements or specimen validity guidance is present in the specimen.

(d) If you suspect the presence of an interfering substance/adulterant that could make a test result invalid, but you are unable to identify it (*e.g.,* a new adulterant), you may, as the first laboratory, send the specimen to another HHS certified laboratory that has the capability of doing so.

(e) If you identify a substance in a specimen that appears to be an adulterant, but which is not listed in current HHS requirements or guidance, you must report the finding in writing to ODAPC and the Division of Workplace Programs, HHS, within three business days. You must also complete testing of the specimen for drugs, to the extent technically feasible.

(f) You must conserve as much as possible of the specimen for possible future testing.

§ 40.209 What criteria do laboratories use to establish that a specimen is dilute or substituted?

(a) As a laboratory you must consider the primary specimen to be dilute if the creatinine concentration is less than 20 mg/dL *and* the specific gravity is less than 1.003, unless the criteria for a substituted specimen are met.

(b) As a laboratory you must consider the primary specimen to be substituted if the creatinine concentration is less than or equal to 5 mg/dL *and* the specific gravity is less than or equal to 1.001 or greater than or equal to 1.020.

§ 40.211 What criteria do laboratories use to establish that a specimen is adulterated?

(a) As a laboratory, you must consider the primary specimen to be adulterated if you determine that—

(1) A substance that is not expected to be present in human urine is identified in the specimen;

(2) A substance that is expected to be present in human urine is identified at a concentration so high that it is not consistent with human urine; or

(3) The physical characteristics of the specimen are outside the normal expected range for human urine.

(b) In making your determination under paragraph (a) of this section, you must apply the criteria in current HHS requirements or specimen validity guidance.

§ 40.213 How long does the laboratory retain specimens after testing?

(a) As a laboratory testing the primary specimen, you must retain a specimen that was reported with positive, adulterated, substituted, or invalid results for a minimum of one year.

(b) You must keep such a specimen in secure, long-term, frozen storage in accordance with HHS requirements.

(c) Within the one-year period, the MRO, the employee, the employer, or a DOT agency may request in writing that you retain a specimen for an additional period of time (*e.g.,* for the purpose of preserving evidence for litigation or a safety investigation). If you receive such a request, you must comply with it. If you do not receive such a request, you may discard the specimen at the end of the year.

(d) If you have not sent the split specimen to another laboratory for testing, you must retain the split specimen for an employee's test for the same period of time that you retain the primary specimen and under the same storage conditions.

(e) As the laboratory testing the split specimen, you must meet the requirements of paragraphs (a) through (c) of this section with respect to the split specimen.

§ 40.215 On what basis does the MRO verify test results involving adulteration or substitution?

(a) As an MRO, when you receive a laboratory report that a specimen is adulterated or substituted, you must treat that report in the same way you treat the laboratory's report of a confirmed positive test for a drug or drug metabolite.

(b) You must follow the same procedures used for verification of a confirmed positive test for a drug or drug except as otherwise provided in this section.

(c) In the verification interview, you must explain the laboratory findings to the employee and address technical questions or issues the employee may raise.

(d) You must offer the employee the opportunity to present a legitimate medical explanation for the laboratory findings with respect to presence of the adulterant in, or the creatinine and specific gravity findings for, the specimen.

(e) The employee has the burden of proof that there is a legitimate medical explanation.

(1) To meet this burden in the case of an adulterated specimen, the employee must demonstrate that the adulterant found by the laboratory entered the specimen through physiological means.

(2) To meet this burden in the case of a substituted specimen, the employee must demonstrate that he or she did produce or could have produced urine, through physiological means, meeting the creatinine and specific gravity criteria of § 40.209(b).

(3) The employee must present information meeting this burden at the time of the verification interview. As the MRO, you have discretion to extend the time available to the employee for this purpose for up to five days before verifying the specimen, if you determine that there is a reasonable basis to believe that the employee will be able to produce relevant evidence supporting a legitimate medical explanation within that time.

(f) As the MRO or the employer, you are not responsible for arranging, conducting, or paying for any studies, examinations or analyses to determine whether a legitimate medical explanation exists.

(g) As the MRO, you must exercise your best professional judgment in deciding whether the employee has established a legitimate medical explanation.

(1) If you determine that the employee's explanation does not present a reasonable basis for concluding that there may be a legitimate medical explanation, you must report the test to the DER as a verified refusal to test because of adulteration or substitution, as applicable.

(2) If you believe that the employee's explanation may present a reasonable basis for concluding that there is a legitimate medical explanation, you must direct the employee to obtain, within the five-day period set forth in paragraph (e)(3) of this section, a further medical evaluation. This evaluation must be performed by a licensed physician (the ''referral physician''), acceptable to you, with expertise in the medical issues raised by the employee's explanation. (The MRO may perform this evaluation if the MRO has appropriate expertise.)

(i) As the MRO or employer, you are not responsible for finding or paying a referral physician. However, on request of the employee, you must provide reasonable assistance to the employee's efforts to find such a physician. The final choice of the referral physician is the employee's, as long as the physician is acceptable to you.

(ii) As the MRO, you must consult with the referral physician, providing guidance to him or her concerning his or her responsibilities under this section. As part of this consultation, you must provide the following information to the referral physician:

(A) That the employee was required to take a DOT drug test, but the laboratory reported that the specimen was adulterated or substituted, which is treated as a refusal to test;

(B) The consequences of the appropriate DOT agency regulation for refusing to take the required drug test;

(C) That the referral physician must agree to follow the requirements of paragraphs (g)(3) through (g)(4) of this section; and

(D) That the referral physician must provide you with a signed statement of his or her recommendations.

(3) As the referral physician, you must evaluate the employee and consider any evidence the employee presents concerning the employee's medical explanation. You may conduct additional tests to determine whether there is a legitimate medical explanation. Any additional urine tests must be performed in an HHS-certified laboratory.

(4) As the referral physician, you must then make a written recommendation to the MRO about whether the MRO should determine that there is a legitimate medical explanation. As the MRO, you must seriously consider and assess the referral physician's recommendation in deciding whether there is a legitimate medical explanation.

(5) As the MRO, if you determine that there is a legitimate medical explanation, you must cancel the test and inform ODAPC in writing of the determination and the basis for it (*e.g.,* referral physician's findings, evidence produced by the employee).

(6) As the MRO, if you determine that there is not a legitimate medical explanation, you must report the test to the DER as a verified refusal to test because of adulteration or substitution.

(h) The following are examples of types of evidence an employee could present to support an assertion of a legitimate medical explanation for a substituted result:

(1) Medically valid evidence demonstrating that the employee is capable of physiologically producing urine meeting the creatinine and specific gravity criteria of § 40.209(b).

(i) To be regarded as medically valid, the evidence must have been gathered using appropriate methodology and controls to ensure its accuracy and reliability.

(ii) Assertion by the employee that his or her personal characteristics (*e.g.,* with respect to race, gender, weight, diet, working conditions) are responsible for the substituted result does not, in itself, constitute a legitimate medical explanation. To make a case that there is a legitimate medical explanation, the employee must present evidence showing that the cited personal characteristics actually result in the physiological production of urine meeting the creatinine and specific gravity criteria of § 40.209 (b).

(2) Information from a medical evaluation under paragraph (g) of this section that the individual has a medical condition that has been demonstrated to cause the employee to physiologically produce urine meeting the creatinine and specific gravity criteria of § 40.209(b).

(i) A finding or diagnosis by the physician that an employee has a medical condition, in itself, does not constitute a legitimate medical explanation.

(ii) To establish there is a legitimate medical explanation, the employee must demonstrate that the cited medical condition actually results in the physiological production of urine meeting the creatinine and specific gravity criteria of § 40.209(b).

§ 40.217 What does the second laboratory do with the split specimen when it is tested to reconfirm an adulterated test result?

As the laboratory testing the split specimen, you must test the split specimen for the adulterant detected in the primary specimen using the same criteria that were used for the primary specimen or HHS guidance, as applicable. The result of the primary specimen is reconfirmed if the split specimen meets these criteria.

§ 40.219 What does the second laboratory do with the split specimen when it is tested to reconfirm a substituted test result?

As the laboratory testing the split specimen, you must test the split specimen using the criteria of § 40.209(b), just as you would do for a primary specimen. The result of the primary specimen is reconfirmed if the split specimen meets these criteria.

§ 40.221 What information do laboratories report to MROs regarding split specimen results?

(a) As the laboratory responsible for testing the split specimen, and you are using the Federal Testing Custody and Control Form (CCF) issued by HHS on June 23, 2000, you must report split specimen test results in adulteration and substitution situations by checking the ''Reconfirmed'' box or the ''Failed to Reconfirm'' box (Step 5(b)) on Copy 1 of the CCF.

(b) If you check the ''Failed to Reconfirm'' box, one of the following statements must be included (as appropriate) on the ''Reason'' line (Step 5(b)):

(1) Drug(s)/metabolite(s) not detected.''

(2) ''Adulterant not found within criteria.''

(3) ''Specimen not consistent with substitution criteria [specify creatinine, specific gravity, or both]''

(4) ''Specimen not available for testing.''

(c) If you are using the CCF issued by HHS prior to June 23, 2000, enter the information referenced in paragraph (b) (2), (3), or (4) of this section on the ''remarks'' line.

(d) As the laboratory certifying scientist, enter your name, sign, and date the CCF.

§ 40.223 What does the MRO do with split specimen laboratory results?

As an MRO, you must take the following actions when a laboratory reports the following results of split specimen tests concerning adulterated or substituted specimens:

(a) *Reconfirmed.* (1) In the case of a reconfirmed positive test for a drug or drug metabolite, report the reconfirmation to the DER and the employee.

(2) In the case of a reconfirmed adulterated or substituted result, report to the DER and the employee that the specimen was adulterated or substituted, either of which constitutes a refusal to test. Therefore, ''refusal to test'' is the final result.

(b) *Failed to Reconfirm: Drug(s)/Drug Metabolite(s) Not Detected.* (1) Report to the DER and the employee that both tests must be cancelled.

(2) Inform ODAPC of the failure to reconfirm.

(c) *Failed to Reconfirm: Adulterated or Substituted (as appropriate); Criteria Not Met.* (1) Report to the DER and the employee that both tests must be cancelled.

(2) Inform ODAPC of the failure to reconfirm.

(d) *Failed to Reconfirm: Specimen not Available for Testing.* (1) Report to the DER and the employee that both tests must be cancelled and the reason for cancellation.

(2) Direct the DER to ensure the immediate collection of another specimen from the employee under direct observation, with no notice given to the employee of this collection requirement until immediately before the collection.

(3) Inform ODAPC of the failure to reconfirm.

(e) Enter your name, sign and date the appropriate copy of the CCF.

(f) Send a legible copy of the appropriate copy of the CCF (or a signed and dated letter) to the employer and keep a copy for your records.

§ 40.225 What is a refusal to take a DOT drug test, and what are the consequences?

(a) [Reserved]

(b) As an employee, if the MRO reports that you have a verified adulterated or substituted test result, you have refused to take a drug test.

(c) As an employee, if you refuse to take a drug test, you incur the consequences specified under DOT agency regulations for a violation of those DOT agency regulations.

(d) [Reserved]

(e) [Reserved]

Subpart F—Public Interest Exclusions

§§ 40.301–40.359 [Reserved]

§ 40.361 What is the purpose of a public interest exclusion (PIE)?

(a) To protect the public interest, including protecting transportation employers and employees from serious noncompliance with DOT drug and alcohol testing rules, the Department's policy is to ensure that employers conduct business only with responsible service agents.

(b) The Department therefore uses PIEs to exclude from participation in DOT's drug and alcohol testing program any service agent who, by serious noncompliance with this part or other DOT agency drug and alcohol testing regulations, has shown that it is not currently acting in a responsible manner.

(c) A PIE is a serious action that the Department takes only to protect the public interest. We intend to use PIEs only to remedy situations of serious noncompliance. PIEs are not used for the purpose of punishment.

(d) Nothing in this subpart precludes a DOT agency or the Inspector General from taking other action authorized by its regulations with respect to service agents or employers that violate its regulations.

§ 40.363 On what basis may the Department issue a PIE?

(a) If you are a service agent, the Department may issue a PIE concerning you if we determine that you have failed or refused to provide drug or alcohol testing services consistent with the requirements of this part or a DOT agency drug and alcohol regulation.

(b) The Department also may issue a PIE if you have failed to cooperate with DOT agency representatives concerning inspections, complaint investigations, compliance and enforcement reviews, or requests for documents and other information about compliance with this part or DOT agency drug and alcohol regulations.

§ 40.365 What is the Department's policy concerning starting a PIE proceeding?

(a) It is the Department's policy to start a PIE proceeding only in cases of serious, uncorrected noncompliance with the provisions of this part, affecting such matters as safety, the outcomes of test results, privacy and confidentiality, due process and fairness for employees, the honesty and integrity of the testing program, and cooperation with or provision of information to DOT agency representatives.

(b) The following are examples of the kinds of serious noncompliance that, as a matter of policy, the Department views as appropriate grounds for starting a PIE proceeding. These examples are not intended to be an exhaustive or exclusive list of the grounds for starting a PIE proceeding. We intend them to illustrate the level of seriousness that the Department believes supports starting a PIE proceeding. The examples follow:

(1) For an MRO, verifying tests positive without interviewing the

employees as required by this part or providing MRO services without meeting the qualifications for an MRO required by this part;

(2) For a laboratory, refusing to provide information to the Department, an employer, or an employee as required by this part; or a pattern or practice of testing errors that result in the cancellation of tests. (As a general matter of policy, the Department does not intend to initiate a PIE proceeding concerning a laboratory with respect to matters on which HHS initiates certification actions under its laboratory guidelines.);

(3) For a collector, a pattern or practice of directly observing collections when doing so is unauthorized, or failing or refusing to directly observe collections when doing so is mandatory;

(4) For collectors, BATs, or STTs, a pattern or practice of using forms, testing equipment, or collection kits that do not meet the standards in this part;

(5) For a collector, BAT, or STT, a pattern or practice of ''fatal flaws'' or other significant uncorrected errors in the collection process;

(6) For a laboratory, MRO or C/TPA, failing or refusing to report tests results as required by this part or DOT agency regulations;

(7) For a laboratory, falsifying, concealing, or destroying documentation concerning any part of the drug testing process, including, but not limited to, documents in a ''litigation package'';

(8) For SAPs, providing SAP services while not meeting SAP qualifications required by this part or performing evaluations without face-to-face interviews;

(9) For any service agent, maintaining a relationship with another party that constitutes a conflict of interest under this part (*e.g.,* a laboratory that derives a financial benefit from having an employer use a specific MRO);

(10) For any service agent, representing falsely that the service agent or its activities is approved or certified by the Department or a DOT agency;

(11) For any service agent, disclosing an employee's test result information to any party this part or a DOT agency regulation does not authorize, including by obtaining a ''blanket'' consent from employees or by creating a data base from which employers or others can retrieve an employee's DOT test results without the specific consent of the employee;

(12) For any service agent, interfering or attempting to interfere with the ability of an MRO to communicate with the Department, or retaliating against an MRO for communicating with the Department;

(13) For any service agent, directing or recommending that an employer fail or refuse to implement any provision of this part; or

(14) With respect to noncompliance with a DOT agency regulation, conduct that affects important provisions of Department-wide concern (*e.g.,* failure to properly conduct the selection process for random testing).

§ 40.367 Who initiates a PIE proceeding?

The following DOT officials may initiate a PIE proceeding:

(a) The drug and alcohol program manager of a DOT agency;

(b) An official of ODAPC, other than the Director; or

(c) The designee of any of these officials.

§ 40.369 What is the discretion of an initiating official in starting a PIE proceeding?

(a) Initiating officials have broad discretion in deciding whether to start a PIE proceeding.

(b) In exercising this discretion, the initiating official must consider the Department's policy regarding the seriousness of the service agent's conduct (see § 40.365) and all information he or she has obtained to this point concerning the facts of the case. The initiating official may also consider the availability of the resources needed to pursue a PIE proceeding.

(c) A decision not to initiate a PIE proceeding does not necessarily mean that the Department regards a service agent as being in compliance or that the Department may not use other applicable remedies in a situation of noncompliance.

§ 40.371 On what information does an initiating official rely in deciding whether to start a PIE proceeding?

(a) An initiating official may rely on credible information from any source as the basis for starting a PIE proceeding.

(b) Before sending a correction notice (see § 40.373), the initiating official informally contacts the service agent to determine if there is any information that may affect the initiating official's determination about whether it is necessary to send a correction notice. The initiating official may take any information resulting from this contact into account in determining whether to proceed under this subpart.

§ 40.373 Before starting a PIE proceeding, does the initiating official give the service agent an opportunity to correct problems?

(a) If you are a service agent, the initiating official must send you a correction notice before starting a PIE proceeding.

(b) The correction notice identifies the specific areas in which you must come into compliance in order to avoid being subject to a PIE proceeding.

(c) If you make and document changes needed to come into compliance in the areas listed in the correction notice to the satisfaction of the initiating official within 60 days of the date you receive the notice, the initiating official does not start a PIE proceeding. The initiating official may conduct appropriate fact finding to verify that you have made and maintained satisfactory corrections. When he or she is satisfied that you are in compliance, the initiating official sends you a notice that the matter is concluded.

§ 40.375 How does the initiating official start a PIE proceeding?

(a) As a service agent, if your compliance matter is not correctable (see § 40.373(a)), or if have not resolved compliance matters as provided in § 40.373(c), the initiating official starts a PIE proceeding by sending you a notice of proposed exclusion (NOPE). The NOPE contains the initiating official's recommendations concerning the issuance of a PIE, but it is not a decision by the Department to issue a PIE.

(b) The NOPE includes the following information:

(1) A statement that the initiating official is recommending that the Department issue a PIE concerning you;

(2) The factual basis for the initiating official's belief that you are not providing drug and/or alcohol testing services to DOT-regulated employers consistent with the requirements of this part or are in serious noncompliance with a DOT agency drug and alcohol regulation;

(3) The factual basis for the initiating official's belief that your noncompliance has not been or cannot be corrected;

(4) The initiating official's recommendation for the scope of the PIE;

(5) The initiating official's recommendation for the duration of the PIE; and

(6) A statement that you may contest the issuance of the proposed PIE, as provided in § 40.379.

(c) The initiating official sends a copy of the NOPE to the ODAPC Director at the same time he or she sends the NOPE to you.

§ 40.377 Who decides whether to issue a PIE?

(a) The ODAPC Director, or his or her designee, decides whether to issue a PIE. If a designee is acting as the

decisionmaker, all references in this subpart to the Director refer to the designee.

(b) To ensure his or her impartiality, the Director plays no role in the initiating official's determination about whether to start a PIE proceeding.

(c) There is a ''firewall'' between the initiating official and the Director. This means that the initiating official and the Director are prohibited from having any discussion, contact, or exchange of information with one another about the matter, except for documents and discussions that are part of the record of the proceeding.

§ 40.379 How do you contest the issuance of a PIE?

(a) If you receive a NOPE, you may contest the issuance of the PIE.

(b) If you want to contest the proposed PIE, you must provide the Director information and argument in opposition to the proposed PIE in writing, in person, and/or through a representative. To contest the proposed PIE, you must take one or more of the steps listed in this paragraph (b) within 30 days after you receive the NOPE.

(1) You may request that the Director dismiss the proposed PIE without further proceedings, on the basis that it does not concern serious noncompliance with this part or DOT agency regulations, consistent with the Department's policy as stated in § 40.365.

(2) You may present written information and arguments, consistent with the provisions of § 40.381, contesting the proposed PIE.

(3) You may arrange with the Director for an informal meeting to present your information and arguments.

(c) If you do not take any of the actions listed in paragraph (b) of this section within 30 days after you receive the NOPE, the matter proceeds as an uncontested case. In this event, the Director makes his or her decision based on the record provided by the initiating official (*i.e.,* the NOPE and any supporting information or testimony) and any additional information the Director obtains.

§ 40.381 What information do you present to contest the proposed issuance of a PIE?

(a) As a service agent who wants to contest a proposed PIE, you must present at least the following information to the Director:

(1) Specific facts that contradict the statements contained in the NOPE (see § 40.375(b)(2) and (3)). A general denial is insufficient to raise a genuine dispute over facts material to the issuance of a PIE;

(2) Identification of any existing, proposed or prior PIE; and

(3) Identification of your affiliates, if any.

(b) You may provide any information and arguments you wish concerning the proposed issuance, scope and duration of the PIE (see § 40.375(b)(4) and (5).

(c) You may provide any additional relevant information or arguments concerning any of the issues in the matter.

§ 40.383 What procedures apply if you contest the issuance of a PIE?

(a) DOT conducts PIE proceedings in a fair and informal manner. The Director may use flexible procedures to allow you to present matters in opposition. The Director is not required to follow formal rules of evidence or procedure in creating the record of the proceeding.

(b) The Director will consider any information or argument he or she determines to be relevant to the decision on the matter.

(c) You may submit any documentary evidence you want the Director to consider. In addition, if you have arranged an informal meeting with the Director, you may present witnesses and confront any person the initiating official presents as a witness against you.

(d) In cases where there are material factual issues in dispute, the Director or his or her designee may conduct additional fact-finding.

(e) If you have arranged a meeting with the Director, the Director will make a transcribed record of the meeting available to you on your request. You must pay the cost of transcribing and copying the meeting record.

§ 40.385 Who bears the burden of proof in a PIE proceeding?

(a) As the proponent of issuing a PIE, the initiating official bears the burden of proof.

(b) This burden is to demonstrate, by a preponderance of the evidence, that the service agent was in serious noncompliance with the requirements of this part for drug and/or alcohol testing-related services or with the requirements of another DOT agency drug and alcohol testing regulation.

§ 40.387 What matters does the Director decide concerning a proposed PIE?

(a) Following the service agent's response (see § 40.379(b)) or, if no response is received, after 30 days have passed from the date on which the service agent received the NOPE, the Director may take one of the following steps:

(1) In response to a request from the service agent (see § 40.379(b)(1)) or on his or her own motion, the Director may dismiss a PIE proceeding if he or she determines that it does not concern serious noncompliance with this part or DOT agency regulations, consistent with the Department's policy as stated in § 40.365.

(i) If the Director dismisses a proposed PIE under this paragraph (a), the action is closed with respect to the noncompliance alleged in the NOPE.

(ii) The Department may initiate a new PIE proceeding against you on the basis of different or subsequent conduct that is in noncompliance with this part or other DOT drug and alcohol testing rules.

(2) If the Director determines that the initiating official's submission does not have complete information needed for a decision, the Director may remand the matter to the initiating official. The initiating official may resubmit the matter to the Director when the needed information is complete. If the basis for the proposed PIE has changed, the initiating official must send an amended NOPE to the service agent.

(b) The Director makes determinations concerning the following matters in any PIE proceeding that he or she decides on the merits:

(1) Any material facts that are in dispute;

(2) Whether the facts support issuing a PIE;

(3) The scope of any PIE that is issued; and

(4) The duration of any PIE that is issued.

§ 40.389 What factors may the Director consider?

This section lists examples of the kind of mitigating and aggravating factors that the Director may consider in determining whether to issue a PIE concerning you, as well as the scope and duration of a PIE. This list is not exhaustive or exclusive. The Director may consider other factors if appropriate in the circumstances of a particular case. The list of examples follows:

(a) The actual or potential harm that results or may result from your noncompliance;

(b) The frequency of incidents and/or duration of the noncompliance;

(c) Whether there is a pattern or prior history of noncompliance;

(d) Whether the noncompliance was pervasive within your organization, including such factors as the following:

(1) Whether and to what extent your organization planned, initiated, or carried out the noncompliance;

(2) The positions held by individuals involved in the noncompliance, and

whether your principals tolerated their noncompliance; and

(3) Whether you had effective standards of conduct and control systems (both with respect to your own organization and any contractors or affiliates) at the time the noncompliance occurred;

(e) Whether you have demonstrated an appropriate compliance disposition, including such factors as the following:

(1) Whether you have accepted responsibility for the noncompliance and recognize the seriousness of the conduct that led to the cause for issuance of the PIE;

(2) Whether you have cooperated fully with the Department during the investigation. The Director may consider when the cooperation began and whether you disclosed all pertinent information known to you;

(3) Whether you have fully investigated the circumstances of the noncompliance forming the basis for the PIE and, if so, have made the result of the investigation available to the Director;

(4) Whether you have taken appropriate disciplinary action against the individuals responsible for the activity that constitutes the grounds for issuance of the PIE; and

(5) Whether your organization has taken appropriate corrective actions or remedial measures, including implementing actions to prevent recurrence;

(f) With respect to noncompliance with a DOT agency regulation, the degree to which the noncompliance affects matters common to the DOT drug and alcohol testing program;

(g) Other factors appropriate to the circumstances of the case.

§ 40.391 What is the scope of a PIE?

(a) The scope of a PIE is the Department's determination about the divisions, organizational elements, types of services, affiliates, and/or individuals (including direct employees of a service agent and its contractors) to which a PIE applies.

(b) If, as a service agent, the Department issues a PIE concerning you, the PIE applies to all your divisions, organizational elements, and types of services that are involved with or affected by the noncompliance that forms the factual basis for issuing the PIE.

(c) In the NOPE (see § 40.375(b)(4)), the initiating official sets forth his or her recommendation for the scope of the PIE. The proposed scope of the PIE is one of the elements of the proceeding that the service agent may contest (see § 40.381(b)) and about which the Director makes a decision (see § 40.387(b)(3)).

(d) In recommending and deciding the scope of the PIE, the initiating official and Director, respectively, must take into account the provisions of paragraphs (e) through (j) of this section.

(e) The pervasiveness of the noncompliance within a service agent's organization (see § 40.389(d)) is an important consideration in determining the scope of a PIE. The appropriate scope of a PIE grows broader as the pervasiveness of the noncompliance increases.

(f) The application of a PIE is not limited to the specific location or employer at which the conduct that forms the factual basis for issuing the PIE was discovered.

(g) A PIE applies to your affiliates, if the affiliate is involved with or affected by the conduct that forms the factual basis for issuing the PIE.

(h) A PIE applies to individuals who are officers, employees, directors, shareholders, partners, or other individuals associated with your organization in the following circumstances:

(1) Conduct forming any part of the factual basis of the PIE occurred in connection with the individual's performance of duties by or on behalf of your organization; or

(2) The individual knew of, had reason to know of, approved, or acquiesced in such conduct. The individual's acceptance of benefits derived from such conduct is evidence of such knowledge, acquiescence, or approval.

(i) If a contractor to your organization is solely responsible for the conduct that forms the factual basis for a PIE, the PIE does not apply to the service agent itself unless the service agent knew or should have known about the conduct and did not take action to correct it.

(j) PIEs do not apply to drug and alcohol testing that DOT does not regulate.

(k) The following examples illustrate how the Department intends the provisions of this section to work:

Example 1 to § 40.391. Service Agent P provides a variety of drug testing services. P's SAP services are involved in a serious violation of this Part 40. However, P's other services fully comply with this part, and P's overall management did not plan or concur in the noncompliance, which in fact was contrary to P's articulated standards. Because the noncompliance was isolated in one area of the organization's activities, and did not pervade the entire organization, the scope of the PIE could be limited to SAP services.

Example 2 to § 40.391. Service Agent Q provides a similar variety of services. The conduct forming the factual basis for a PIE concerns collections for a transit authority. As in Example 1, the noncompliance is not pervasive throughout Q's organization. The PIE would apply to collections at all locations served by Q, not just the particular transit authority or not just in the state in which the transit authority is located.

Example 3 to § 40.391. Service Agent R provides a similar array of services. One or more of the following problems exists: R's activities in several areas—collections, MROs, SAPs, protecting the confidentiality of information—are involved in serious noncompliance; DOT determines that R's management knew or should have known about serious noncompliance in one or more areas, but management did not take timely corrective action; or, in response to an inquiry from DOT personnel, R's management refuses to provide information about its operations. In each of these three cases, the scope of the PIE would include all aspects of R's services.

Example 4 to § 40.391. Service Agent W provides only one kind of service (*e.g.,* laboratory or MRO services). The Department issues a PIE concerning these services. Because W only provides this one kind of service, the PIE necessarily applies to all its operations.

Example 5 to § 40.391. Service Agent X, by exercising reasonably prudent oversight of its collection contractor, should have known that the contractor was making numerous ''fatal flaws'' in tests. Alternatively, X received a correction notice pointing out these problems in its contractor's collections. In neither case did X take action to correct the problem. X, as well as the contractor, would be subject to a PIE with respect to collections.

Example 6 to § 40.391. Service Agent Y could not reasonably have known that one of its MROs was regularly failing to interview employees before verifying tests positive. When it received a correction notice, Y immediately dismissed the erring MRO. In this case, the MRO would be subject to a PIE but Y would not.

Example 7 to § 40.391. The Department issues a PIE with respect to Service Agent Z. Z provides services for DOT-regulated transportation employers, a Federal agency under the HHS-regulated Federal employee testing program, and various private businesses and public agencies that DOT does not regulate. The PIE applies only to the DOT-regulated transportation employers with respect to their DOT-mandated testing, not to the Federal agency or the other public agencies and private businesses. The PIE does not prevent the non-DOT regulated entities from continuing to use Z's services.

§ 40.393 How long does a PIE stay in effect?

(a) In the NOPE (see § 40.375(b)(5)), the initiating official proposes the duration of the PIE. The duration of the PIE is one of the elements of the proceeding that the service agent may contest (see § 40.381(b)) and about which the Director makes a decision (see § 40.387(b)(4)).

(b) In deciding upon the duration of the PIE, the Director considers the

seriousness of the conduct on which the PIE is based and the continued need to protect employers and employees from the service agent's noncompliance. The Director considers factors such as those listed in § 40.389 in making this decision.

(c) The duration of a PIE will be between one and five years, unless the Director reduces its duration under § 40.407.

§ 40.395 Can you settle a PIE proceeding?

At any time before the Director's decision, you and the initiating official can, with the Director's concurrence, settle a PIE proceeding.

§ 40.397 When does the Director make a PIE decision?

The Director makes his or her decision within 60 days of the date when the record of a PIE proceeding is complete (including any meeting with the Director and any additional fact-finding that is necessary). The Director may extend this period for good cause for additional periods of up to 30 days.

§ 40.399 How does the Department notify service agents of its decision?

If you are a service agent involved in a PIE proceeding, the Director provides you written notice as soon as he or she makes a PIE decision. The notice includes the following elements:

(a) If the decision is not to issue a PIE, a statement of the reasons for the decision, including findings of fact with respect to any material factual issues that were in dispute.

(b) If the decision is to issue a PIE—

(1) A reference to the NOPE;

(2) A statement of the reasons for the decision, including findings of fact with respect to any material factual issues that were in dispute;

(3) A statement of the scope of the PIE; and

(4) A statement of the duration of the PIE.

§ 40.401 How does the Department notify employers and the public about a PIE?

(a) The Department maintains a document called the ''List of Excluded Drug and Alcohol Service Agents.'' This document may be found on the Department's web site (http://www.dot.gov/ost/dapc). You may also request a copy of the document from ODAPC.

(b) When the Director issues a PIE, he or she adds to the List the name and address of the service agent, and any other persons or organizations, to whom the PIE applies and information about the scope and duration of the PIE.

(c) When a service agent ceases to be subject to a PIE, the Director removes this information from the List.

(d) The Department also publishes a **Federal Register** notice to inform the public on any occasion on which a service agent is added to or taken off the List.

§ 40.403 Must a service agent notify its clients when the Department issues a PIE?

(a) As a service agent, if the Department issues a PIE concerning you, you must notify each of your DOT-regulated employer clients, in writing, about the issuance, scope, duration, and effect of the PIE. You may meet this requirement by sending a copy of the Director's PIE decision or by a separate notice. You must send this notice to each client within three working days of receiving from the Department the notice provided for in § 40.399(b).

(b) As part of the notice you send under paragraph (a) of this section, you must offer to transfer immediately all records pertaining to the employer and its employees to the employer or to any other service agent the employer designates. You must carry out this transfer as soon as the employer requests it.

§ 40.405 May the Federal courts review PIE decisions?

The Director's decision is a final administrative action of the Department. Like all final administrative actions of Federal agencies, the Director's decision is subject to judicial review under the Administrative Procedure Act (5 U.S.C. 551 *et seq.*).

§ 40.407 May a service agent ask to have a PIE reduced or terminated?

(a) Yes, as a service agent concerning whom the Department has issued a PIE, you may request that the Director terminate a PIE or reduce its duration and/or scope. This process is limited to the issues of duration and scope. It is not an appeal or reconsideration of the decision to issue the PIE.

(b) Your request must be in writing and supported with documentation.

(c) You must wait at least nine months from the date on which the Director issued the PIE to make this request.

(d) The initiating official who was the proponent of the PIE may provide information and arguments concerning your request to the Director.

(e) If the Director verifies that the sources of your noncompliance have been eliminated and that all drug or alcohol testing-related services you would provide to DOT-regulated employers will be consistent with the requirements of this part, the Director may issue a notice terminating or reducing the PIE.

§ 40.409 What does the issuance of a PIE mean to transportation employers?

(a) As an employer, you are deemed to have notice of the issuance of a PIE when it appears on the List mentioned in § 40.401(a) or the notice of the PIE appears in the **Federal Register** as provided in § 40.401(d). You should check this List to ensure that any service agents you are using or planning to use are not subject to a PIE.

(b) As an employer who is using a service agent concerning whom a PIE is issued, you must stop using the services of the service agent no later than 90 days after the Department has published the decision in the **Federal Register** or posted it on its web site. You may apply to the ODAPC Director for an extension of 30 days if you demonstrate that you cannot find a substitute service agent within 90 days.

(c) Except during the period provided in paragraph (b) of this section, you must not, as an employer, use the services of a service agent that are covered by a PIE that the Director has issued under this subpart. If you do so, you are in violation of the Department's regulations and subject to applicable DOT agency sanctions (*e.g.,* civil penalties, withholding of Federal financial assistance).

(d) You also must not obtain drug or alcohol testing services through a contractor or affiliate of the service agent to whom the PIE applies.

Example to Paragraph (d). Service Agent R was subject to a PIE with respect to SAP services. As an employer, not only must you not use R's own SAP services, but you also must not use SAP services you arrange through R, such as services provided by a subcontractor or affiliate of R or a person or organization that receives financial gain from its relationship with R.

(e) This section's prohibition on using the services of a service agent concerning which the Director has issued a PIE applies to employers in all industries subject to DOT drug and alcohol testing regulations.

Example to Paragraph (e). The initiating official for a PIE was the FAA drug and alcohol program manager, and the conduct forming the basis of the PIE pertained to the aviation industry. As a motor carrier, transit authority, pipeline, railroad, or maritime employer, you are also prohibited from using the services of the service agent involved in connection with the DOT drug and alcohol testing program.

(f) The issuance of a PIE does not result in the cancellation of drug or alcohol tests conducted using the service agent involved before the

issuance of the Director's decision or up to 90 days following its publication in the **Federal Register** or posting on the Department's web site, unless otherwise specified in the Director's PIE decision or the Director grants an extension as provided in paragraph (b) of this section.

Example to Paragraph (f). The Department issues a PIE concerning Service Agent N on September 1. All tests conducted using N's services before September 1, and through November 30, are valid for all purposes under DOT drug and alcohol testing regulations, assuming they meet all other regulatory requirements.

§ 40.411 What is the role of the DOT Inspector General's office?

(a) Any person may bring concerns about waste, fraud, or abuse on the part of a service agent to the attention of the DOT Office of Inspector General.

(b) In appropriate cases, the Office of Inspector General may pursue criminal or civil remedies against a service agent.

(c) The Office of Inspector General may provide factual information to other DOT officials for use in a PIE proceeding.

§ 40.413 How are notices sent to service agents?

(a) If you are a service agent, DOT sends notices to you, including correction notices, notices of proposed exclusion, decision notices, and other notices, in any of the ways mentioned in paragraph (b) or (c) of this section.

(b) DOT may send a notice to you, your identified counsel, your agent for service of process, or any of your partners, officers, directors, owners, or joint venturers to the last known street address, fax number, or e-mail address. DOT deems the notice to have been received by you if sent to any of these persons.

(c) DOT considers notices to be received by you—

(1) When delivered, if DOT mails the notice to the last known street address, or five days after we send it if the letter is undeliverable;

(2) When sent, if DOT sends the notice by fax or five days after we send it if the fax is undeliverable; or

(3) When delivered, if DOT sends the notice by e-mail or five days after DOT sends it if the e-mail is undeliverable.

2. Effective August 1, 2001, revise 49 CFR Part 40 to read as follows:

PART 40—PROCEDURES FOR TRANSPORTATION WORKPLACE DRUG AND ALCOHOL TESTING PROGRAMS

Subpart A—Administrative Provisions

Sec.

Subpart B—Employer Responsibilities

Subpart C—Urine Collection Personnel

Subpart D—Collection Sites, Forms, Equipment and Supplies Used in DOT Urine Collections

Subpart E—Urine Specimen Collections

Subpart F—Drug Testing Laboratories

Subpart G—Medical Review Officers and the Verification Process

Authority: 49 U.S.C. 102, 301, 322, 5331, 20140, 31306, and 45101 *et seq.*

Subpart A—Administrative Provisions

§ 40.1 Who does this regulation cover?

(a) This part tells all parties who conduct drug and alcohol tests required by Department of Transportation (DOT) agency regulations how to conduct these tests and what procedures to use.

(b) This part concerns the activities of transportation employers, safety-sensitive transportation employees (including self-employed individuals, contractors and volunteers as covered by DOT agency regulations), and service agents.

(c) Nothing in this part is intended to supersede or conflict with the implementation of the Federal Railroad Administration's post-accident testing program (see 49 CFR 219.200).

§ 40.3 What do the terms used in this regulation mean?

In this part, the terms listed in this section have the following meanings:

Adulterated specimen. A specimen that contains a substance that is not expected to be present in human urine, or contains a substance expected to be present but is at a concentration so high that it is not consistent with human urine.

Affiliate. Persons are affiliates of one another if, directly or indirectly, one controls or has the power to control the other, or a third party controls or has the power to control both. Indicators of control include, but are not limited to: interlocking management or ownership; shared interest among family members; shared facilities or equipment; or common use of employees. Following the issuance of a public interest exclusion, an organization having the same or similar management, ownership, or principal employees as the service agent concerning whom a public interest exclusion is in effect is regarded as an affiliate. This definition is used in connection with the public interest exclusion procedures of Subpart R of this part.

Air blank. In evidential breath testing devices (EBTs) using gas chromatography technology, a reading of the device's internal standard. In all other EBTs, a reading of ambient air containing no alcohol.

Alcohol. The intoxicating agent in beverage alcohol, ethyl alcohol or other low molecular weight alcohols, including methyl or isopropyl alcohol.

Alcohol concentration. The alcohol in a volume of breath expressed in terms of grams of alcohol per 210 liters of breath as indicated by a breath test under this part.

Alcohol confirmation test. A subsequent test using an EBT, following a screening test with a result of 0.02 or greater, that provides quantitative data about the alcohol concentration.

Alcohol screening device (ASD). A breath or saliva device, other than an EBT, that is approved by the National Highway Traffic Safety Administration (NHTSA) and placed on a conforming products list (CPL) for such devices.

Alcohol screening test. An analytic procedure to determine whether an employee may have a prohibited concentration of alcohol in a breath or saliva specimen.

Alcohol testing site. A place selected by the employer where employees present themselves for the purpose of providing breath or saliva for an alcohol test.

Alcohol use. The drinking or swallowing of any beverage, liquid mixture or preparation (including any medication), containing alcohol.

Blind specimen or blind performance test specimen. A specimen submitted to a laboratory for quality control testing purposes, with a fictitious identifier, so that the laboratory cannot distinguish it from an employee specimen.

Breath Alcohol Technician (BAT). A person who instructs and assists employees in the alcohol testing process and operates an evidential breath testing device.

Cancelled test. A drug or alcohol test that has a problem identified that cannot be or has not been corrected, or which this part otherwise requires to be cancelled. A cancelled test is neither a positive nor a negative test.

Chain of custody. The procedure used to document the handling of the urine specimen from the time the employee gives the specimen to the collector until the specimen is destroyed. This

procedure uses the Federal Drug Testing Custody and Control Form (CCF).

Collection container. A container into which the employee urinates to provide the specimen for a drug test.

Collection site. A place selected by the employer where employees present themselves for the purpose of providing a urine specimen for a drug test.

Collector. A person who instructs and assists employees at a collection site, who receives and makes an initial inspection of the specimen provided by those employees, and who initiates and completes the CCF.

Confirmation (or confirmatory) drug test. A second analytical procedure performed on a urine specimen to identify and quantify the presence of a specific drug or drug metabolite.

Confirmation (or confirmatory) validity test. A second test performed on a urine specimen to further support a validity test result.

Confirmed drug test. A confirmation test result received by an MRO from a laboratory.

Consortium/Third-party administrator (C/TPA). A service agent that provides or coordinates the provision of a variety of drug and alcohol testing services to employers. C/TPAs typically perform administrative tasks concerning the operation of the employers' drug and alcohol testing programs. This term includes, but is not limited to, groups of employers who join together to administer, as a single entity, the DOT drug and alcohol testing programs of its members. C/TPAs are not ''employers'' for purposes of this part.

Continuing education. Training for medical review officers (MROs) and substance abuse professionals (SAPs) who have completed qualification training and are performing MRO or SAP functions, designed to keep MROs and SAPs current on changes and developments in the DOT drug and alcohol testing program.

Designated employer representative (DER). An employee authorized by the employer to take immediate action(s) to remove employees from safety-sensitive duties and to make required decisions in the testing and evaluation processes. The DER also receives test results and other communications for the employer, consistent with the requirements of this part. Service agents cannot act as DERs.

Dilute specimen. A specimen with creatinine and specific gravity values that are lower than expected for human urine.

DOT, The Department, DOT agency. These terms encompass all DOT agencies, including, but not limited to, the United States Coast Guard (USCG), the Federal Aviation Administration (FAA), the Federal Railroad Administration (FRA), the Federal Motor Carrier Safety Administration (FMCSA), the Federal Transit Administration (FTA), the National Highway Traffic Safety Administration (NHTSA), the Research and Special Programs Administration (RSPA), and the Office of the Secretary (OST). These terms include any designee of a DOT agency.

Drugs. The drugs for which tests are required under this part and DOT agency regulations are marijuana, cocaine, amphetamines, phencyclidine (PCP), and opiates.

Employee. Any person who is designated in a DOT agency regulation as subject to drug testing and/or alcohol testing. The term includes individuals currently performing safety-sensitive functions designated in DOT agency regulations and applicants for employment subject to pre-employment testing. For purposes of drug testing under this part, the term employee has the same meaning as the term ''donor'' as found on CCF and related guidance materials produced by the Department of Health and Human Services.

Employer. A person or entity employing one or more employees (including an individual who is self-employed) subject to DOT agency regulations requiring compliance with this part. The term includes an employer's officers, representatives, and management personnel. Service agents are not employers for the purposes of this part.

Error Correction Training. Training provided to BATs, collectors, and screening test technicians (STTs) following an error that resulted in the cancellation of a drug or alcohol test. Error correction training must be provided in person or by a means that provides real-time observation and interaction between the instructor and trainee.

Evidential Breath Testing Device (EBT). A device approved by NHTSA for the evidential testing of breath at the .02 and .04 alcohol concentrations, placed on NHTSA's Conforming Products List (CPL) for ''Evidential Breath Measurement Devices'' and identified on the CPL as conforming with the model specifications available from NHTSA's Traffic Safety Program.

HHS. The Department of Health and Human Services or any designee of the Secretary, Department of Health and Human Services.

Initial drug test. The test used to differentiate a negative specimen from one that requires further testing for drugs or drug metabolites.

Initial validity test. The first test used to determine if a specimen is adulterated, diluted, or substituted.

Laboratory. Any U.S. laboratory certified by HHS under the National Laboratory Certification Program as meeting the minimum standards of Subpart C of the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs; or, in the case of foreign laboratories, a laboratory approved for participation by DOT under this part. (The HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs are available on the internet at *http://www.health.org/workpl.htm* or from the Division of Workplace Programs, 5600 Fishers Lane, Rockwall II Building, Suite 815, Rockville, MD 20857.)

Medical Review Officer (MRO). A person who is a licensed physician and who is responsible for receiving and reviewing laboratory results generated by an employer's drug testing program and evaluating medical explanations for certain drug test results.

Office of Drug and Alcohol Policy and Compliance (ODAPC). The office in the Office of the Secretary, DOT, that is responsible for coordinating drug and alcohol testing program matters within the Department and providing information concerning the implementation of this part.

Primary specimen. In drug testing, the urine specimen bottle that is opened and tested by a first laboratory to determine whether the employee has a drug or drug metabolite in his or her system; and for the purpose of validity testing. The primary specimen is distinguished from the split specimen, defined in this section.

Qualification Training. The training required in order for a collector, BAT, MRO, SAP, or STT to be qualified to perform their functions in the DOT drug and alcohol testing program. Qualification training may be provided by any appropriate means (*e.g.,* classroom instruction, internet application, CD–ROM, video).

Refresher Training. The training required periodically for qualified collectors, BATs, and STTs to review basic requirements and provide instruction concerning changes in technology (*e.g.,* new testing methods that may be authorized) and amendments, interpretations, guidance, and issues concerning this part and DOT agency drug and alcohol testing regulations. Refresher training can be provided by any appropriate means (*e.g.,* classroom instruction, internet application, CD–ROM, video).

Screening Test Technician (STT). A person who instructs and assists

employees in the alcohol testing process and operates an ASD.

Secretary. The Secretary of Transportation or the Secretary's designee.

Service agent. Any person or entity, other than an employee of the employer, who provides services specified under this part to employers and/or employees in connection with DOT drug and alcohol testing requirements. This includes, but is not limited to, collectors, BATs and STTs, laboratories, MROs, substance abuse professionals, and C/TPAs. To act as service agents, persons and organizations must meet the qualifications set forth in applicable sections of this part. Service agents are not employers for purposes of this part.

Shipping container. A container that is used for transporting and protecting urine specimen bottles and associated documents from the collection site to the laboratory.

Specimen bottle. The bottle that, after being sealed and labeled according to the procedures in this part, is used to hold the urine specimen during transportation to the laboratory.

Split specimen. In drug testing, a part of the urine specimen that is sent to a first laboratory and retained unopened, and which is transported to a second laboratory in the event that the employee requests that it be tested following a verified positive test of the primary specimen or a verified adulterated or substituted test result.

Stand-down. The practice of temporarily removing an employee from the performance of safety-sensitive functions based only on a report from a laboratory to the MRO of a confirmed positive test for a drug or drug metabolite, an adulterated test, or a substituted test, before the MRO has completed verification of the test result.

Substance Abuse Professional (SAP). A person who evaluates employees who have violated a DOT drug and alcohol regulation and makes recommendations concerning education, treatment, follow-up testing, and aftercare.

Substituted specimen. A specimen with creatinine and specific gravity values that are so diminished that they are not consistent with human urine.

Verified test. A drug test result or validity testing result from an HHS-certified laboratory that has undergone review and final determination by the MRO.

§ 40.5 Who issues authoritative interpretations of this regulation?

ODAPC and the DOT Office of General Counsel (OGC) provide written interpretations of the provisions of this part. These written DOT interpretations are the only official and authoritative interpretations concerning the provisions of this part. DOT agencies may incorporate ODAPC/OGC interpretations in written guidance they issue concerning drug and alcohol testing matters. Only Part 40 interpretations issued after August 1, 2001, are considered valid.

§ 40.7 How can you get an exemption from a requirement in this regulation?

(a) If you want an exemption from any provision of this part, you must request it in writing from the Office of the Secretary of Transportation, under the provisions and standards of 49 CFR part 5. You must send requests for an exemption to the following address: Department of Transportation, Deputy Assistant General Counsel for Regulation and Enforcement, 400 7th Street, SW., Room 10424, Washington, DC 20590.

(b) Under the standards of 49 CFR part 5, we will grant the request only if the request documents special or exceptional circumstances, not likely to be generally applicable and not contemplated in connection with the rulemaking that established this part, that make your compliance with a specific provision of this part impracticable.

(c) If we grant you an exemption, you must agree to take steps we specify to comply with the intent of the provision from which an exemption is granted.

(d) We will issue written responses to all exemption requests.

Subpart B—Employer Responsibilities

§ 40.11 What are the general responsibilities of employers under this regulation?

(a) As an employer, you are responsible for meeting all applicable requirements and procedures of this part.

(b) You are responsible for all actions of your officials, representatives, and agents (including service agents) in carrying out the requirements of the DOT agency regulations.

(c) All agreements and arrangements, written or unwritten, between and among employers and service agents concerning the implementation of DOT drug and alcohol testing requirements are deemed, as a matter of law, to require compliance with all applicable provisions of this part and DOT agency drug and alcohol testing regulations. Compliance with these provisions is a material term of all such agreements and arrangements.

§ 40.13 How do DOT drug and alcohol tests relate to non-DOT tests?

(a) DOT tests must be completely separate from non-DOT tests in all respects.

(b) DOT tests must take priority and must be conducted and completed before a non-DOT test is begun. For example, you must discard any excess urine left over from a DOT test and collect a separate void for the subsequent non-DOT test.

(c) Except as provided in paragraph (d) of this section, you must not perform any tests on DOT urine or breath specimens other than those specifically authorized by this part or DOT agency regulations. For example, you may not test a DOT urine specimen for additional drugs, and a laboratory is prohibited from making a DOT urine specimen available for a DNA test or other types of specimen identity testing.

(d) The single exception to paragraph (c) of this section is when a DOT drug test collection is conducted as part of a physical examination required by DOT agency regulations. It is permissible to conduct required medical tests related to this physical examination (*e.g.,* for glucose) on any urine remaining in the collection container after the drug test urine specimens have been sealed into the specimen bottles.

(e) No one is permitted to change or disregard the results of DOT tests based on the results of non-DOT tests. For example, as an employer you must not disregard a verified positive DOT drug test result because the employee presents a negative test result from a blood or urine specimen collected by the employee's physician or a DNA test result purporting to question the identity of the DOT specimen.

(f) As an employer, you must not use the CCF or the ATF in your non-DOT drug and alcohol testing programs. This prohibition includes the use of the DOT forms with references to DOT programs and agencies crossed out. You also must always use the CCF and ATF for all your DOT-mandated drug and alcohol tests.

§ 40.15 May an employer use a service agent to meet DOT drug and alcohol testing requirements?

(a) As an employer, you may use a service agent to perform the tasks needed to comply with this part and DOT agency drug and alcohol testing regulations, consistent with the requirements of Subpart Q and other applicable provisions of this part.

(b) As an employer, you are responsible for ensuring that the service agents you use meet the qualifications set forth in this part (*e.g.,* § 40.121 for MROs). You may require service agents

to show you documentation that they meet the requirements of this part (*e.g.,* documentation of MRO qualifications required by § 40.121(e)).

(c) You remain responsible for compliance with all applicable requirements of this part and other DOT drug and alcohol testing regulations, even when you use a service agent. If you violate this part or other DOT drug and alcohol testing regulations because a service agent has not provided services as our rules require, a DOT agency can subject you to sanctions. Your good faith use of a service agent is not a defense in an enforcement action initiated by a DOT agency in which your alleged noncompliance with this part or a DOT agency drug and alcohol regulation may have resulted from the service agent's conduct.

(d) As an employer, you must not permit a service agent to act as your DER.

§ 40.17 Is an employer responsible for obtaining information from its service agents?

Yes, as an employer, you are responsible for obtaining information required by this part from your service agents. This is true whether or not you choose to use a C/TPA as an intermediary in transmitting information to you. For example, suppose an applicant for a safety-sensitive job takes a pre-employment drug test, but there is a significant delay in your receipt of the test result from an MRO or C/TPA. You must not assume that ''no news is good news'' and permit the applicant to perform safety-sensitive duties before receiving the result. This is a violation of the Department's regulations.

§ 40.19 [Reserved]

§ 40.21 May an employer stand down an employee before the MRO has completed the verification process?

(a) As an employer, you are prohibited from standing employees down, except consistent with a waiver a DOT agency grants under this section.

(b) You may make a request to the concerned DOT agency for a waiver from the prohibition of paragraph (a) of this section. Such a waiver, if granted, permits you to stand an employee down following the MRO's receipt of a laboratory report of a confirmed positive test for a drug or drug metabolite, an adulterated test, or a substituted test pertaining to the employee.

(1) For this purpose, the concerned DOT agency is the one whose drug and alcohol testing rules apply to the majority of the covered employees in your organization. The concerned DOT agency uses its applicable procedures for considering requests for waivers.

(2) Before taking action on a waiver request, the concerned DOT agency coordinates with other DOT agencies that regulate the employer's other covered employees.

(3) The concerned DOT agency provides a written response to each employer that petitions for a waiver, setting forth the reasons for the agency's decision on the waiver request.

(c) Your request for a waiver must include, as a minimum, the following elements:

(1) Information about your organization:

(i) Your determination that standing employees down is necessary for safety in your organization and a statement of your basis for it, including any data on safety problems or incidents that could have been prevented if a stand-down procedure had been in place;

(ii) Data showing the number of confirmed laboratory positive, adulterated, and substituted test results for your employees over the two calendar years preceding your waiver request, and the number and percentage of those test results that were verified positive, adulterated, or substituted by the MRO;

(iii) Information about the work situation of the employees subject to stand-down, including a description of the size and organization of the unit(s) in which the employees work, the process through which employees will be informed of the stand-down, whether there is an in-house MRO, and whether your organization has a medical disqualification or stand-down policy for employees in situations other than drug and alcohol testing; and

(iv) A statement of which DOT agencies regulate your employees.

(2) Your proposed written company policy concerning stand-down, which must include the following elements:

(i) Your assurance that you will distribute copies of your written policy to all employees that it covers;

(ii) Your means of ensuring that no information about the confirmed positive, adulterated, or substituted test result or the reason for the employee's temporary removal from performance of safety-sensitive functions becomes available, directly or indirectly, to anyone in your organization (or subsequently to another employer) other than the employee, the MRO and the DER;

(iii) Your means of ensuring that all covered employees in a particular job category in your organization are treated the same way with respect to stand-down;

(iv) Your means of ensuring that a covered employee will be subject to stand-down only with respect to the actual performance of safety-sensitive duties;

(v) Your means of ensuring that you will not take any action adversely affecting the employee's pay and benefits pending the completion of the MRO's verification process. This includes continuing to pay the employee during the period of the stand-down in the same way you would have paid him or her had he or she not been stood down;

(vi) Your means of ensuring that the verification process will commence no later than the time an employee is temporarily removed from the performance of safety-sensitive functions and that the period of stand-down for any employee will not exceed five days, unless you are informed in writing by the MRO that a longer period is needed to complete the verification process; and

(vii) Your means of ensuring that, in the event that the MRO verifies the test negative or cancels it—

(A) You return the employee immediately to the performance of safety-sensitive duties;

(B) The employee suffers no adverse personnel or financial consequences as a result; and

(C) You maintain no individually identifiable record that the employee had a confirmed laboratory positive, adulterated, or substituted test result (*i.e.,* you maintain a record of the test only as a negative or cancelled test).

(d) The Administrator of the concerned DOT agency, or his or her designee, may grant a waiver request only if he or she determines that, in the context of your organization, there is a high probability that the procedures you propose will effectively enhance safety and protect the interests of employees in fairness and confidentiality.

(1) The Administrator, or his or her designee, may impose any conditions he or she deems appropriate on the grant of a waiver.

(2) The Administrator, or his or her designee, may immediately suspend or revoke the waiver if he or she determines that you have failed to protect effectively the interests of employees in fairness and confidentiality, that you have failed to comply with the requirements of this section, or that you have failed to comply with any other conditions the DOT agency has attached to the waiver.

(e) You must not stand employees down in the absence of a waiver, or inconsistent with the terms of your waiver. If you do, you are in violation

of this part and DOT agency drug testing regulations, and you are subject to enforcement action by the DOT agency just as you are for other violations of this part and DOT agency rules.

§ 40.23 What actions do employers take after receiving verified test results?

(a) As an employer who receives a verified positive drug test result, you must immediately remove the employee involved from performing safety-sensitive functions. You must take this action upon receiving the initial report of the verified positive test result. Do not wait to receive the written report or the result of a split specimen test.

(b) As an employer who receives a verified adulterated or substituted drug test result, you must consider this a refusal to test and immediately remove the employee involved from performing safety-sensitive functions. You must take this action on receiving the initial report of the verified adulterated or substituted test result. Do not wait to receive the written report or the result of a split specimen test.

(c) As an employer who receives an alcohol test result of 0.04 or higher, you must immediately remove the employee involved from performing safety-sensitive functions. If you receive an alcohol test result of 0.02—0.39, you must temporarily remove the employee involved from performing safety-sensitive functions, as provided in applicable DOT agency regulations. Do not wait to receive the written report of the result of the test.

(d) As an employer, when an employee has a verified positive, adulterated, or substituted test result, or has otherwise violated a DOT agency drug and alcohol regulation, you must not return the employee to the performance of safety-sensitive functions until or unless the employee successfully completes the return-to-duty process of Subpart O of this part.

(e) As an employer who receives a drug test result indicating that the employee's specimen was dilute, take action as provided in § 40.197.

(f) As an employer who receives a drug test result indicating that the employee's specimen was invalid and that a second collection must take place under direct observation—

(1) You must immediately direct the employee to provide a new specimen under direct observation.

(2) You must not attach consequences to the finding that the test was invalid other than collecting a new specimen under direct observation.

(3) You must not give any advance notice of this test requirement to the employee.

(4) You must instruct the collector to note on the CCF the same reason (*e.g.* random test, post-accident test) as for the original collection.

(g) As an employer who receives a cancelled test result when a negative result is required (*e.g.*, pre-employment, return-to-duty, or follow-up test), you must direct the employee to provide another specimen immediately.

(h) As an employer, you may also be required to take additional actions required by DOT agency regulations (*e.g.*, FAA rules require some positive drug tests to be reported to the Federal Air Surgeon).

(i) As an employer, you must not alter a drug or alcohol test result transmitted to you by an MRO, BAT, or C/TPA.

§ 40.25 Must an employer check on the drug and alcohol testing record of employees it is intending to use to perform safety-sensitive duties?

(a) Yes, as an employer, you must, after obtaining an employee's written consent, request the information about the employee listed in paragraph (b) of this section. This requirement applies only to employees seeking to begin performing safety-sensitive duties for you for the first time (*i.e.*, a new hire, an employee transfers into a safety-sensitive position). If the employee refuses to provide this written consent, you must not permit the employee to perform safety-sensitive functions.

(b) You must request the information listed in this paragraph (b) from DOT-regulated employers who have employed the employee during any period during the two years before the date of the employee's application or transfer:

(1) Alcohol tests with a result of 0.04 or higher alcohol concentration;

(2) Verified positive drug tests;

(3) Refusals to be tested (including verified adulterated or substituted drug test results);

(4) Other violations of DOT agency drug and alcohol testing regulations; and

(5) With respect to any employee who violated a DOT drug and alcohol regulation, documentation of the employee's successful completion of DOT return-to-duty requirements (including follow-up tests). If the previous employer does not have information about the return-do-duty process (*e.g.*, an employer who did not hire an employee who tested positive on a pre-employment test), you must seek to obtain this information from the employee.

(c) The information obtained from a previous employer includes any drug or alcohol test information obtained from previous employers under this section or other applicable DOT agency regulations.

(d) If feasible, you must obtain and review this information before the employee first performs safety-sensitive functions. If this is not feasible, you must obtain and review the information as soon as possible. However, you must not permit the employee to perform safety-sensitive functions after 30 days from the date on which the employee first performed safety-sensitive functions, unless you have obtained or made and documented a good faith effort to obtain this information.

(e) If you obtain information that the employee has violated a DOT agency drug and alcohol regulation, you must not use the employee to perform safety-sensitive functions unless you also obtain information that the employee has subsequently complied with the return-to-duty requirements of Subpart O of this part and DOT agency drug and alcohol regulations.

(f) You must provide to each of the employers from whom you request information under paragraph (b) of this section written consent for the release of the information cited in paragraph (a) of this section.

(g) The release of information under this section must be in any written form (*e.g.*, fax, e-mail, letter) that ensures confidentiality. As the previous employer, you must maintain a written record of the information released, including the date, the party to whom it was released, and a summary of the information provided.

(h) If you are an employer from whom information is requested under paragraph (b) of this section, you must, after reviewing the employee's specific, written consent, immediately release the requested information to the employer making the inquiry.

(i) As the employer requesting the information required under this section, you must maintain a written, confidential record of the information you obtain or of the good faith efforts you made to obtain the information. You must retain this information for three years from the date of the employee's first performance of safety-sensitive duties for you.

(j) As the employer, you must also ask the employee whether he or she has tested positive, or refused to test, on any pre-employment drug or alcohol test administered by an employer to which the employee applied for, but did not obtain, safety-sensitive transportation work covered by DOT agency drug and alcohol testing rules during the past two years. If the employee admits that he or she had a positive test or a refusal to

test, you must not use the employee to perform safety-sensitive functions for you, until and unless the employee documents successful completion of the return-to-duty process (see paragraphs (b)(5) and (e) of this section).

§ 40.27 Where is other information on employer responsibilities found in this regulation?

You can find other information on the responsibilities of employers in the following sections of this part:

§ 40.3—Definition.
§ 40.35—Information about DERs that employers must provide collectors.
§ 40.45—Modifying CCFs, Use of foreign-language CCFs.
§ 40.47—Use of non-Federal forms for DOT tests or Federal CCFs for non-DOT tests.
§ 40.67—Requirements for direct observation.
§§ 40.103–40.105—Blind specimen requirements.
§ 40. 173—Responsibility to ensure test of split specimen.
§ 40.193—Action in ''shy bladder'' situations.
§ 40.197—Actions following report of a dilute specimen.
§ 40.207—Actions following a report of a cancelled drug test.
§ 40.209—Actions following and consequences of non-fatal flaws in drug tests.
§ 40.215—Information about DERs that employers must provide BATs and STTs.
§ 40.225—Modifying ATFs; use of foreign-language ATFs.
§ 40.227—Use of non-DOT forms for DOT tests or DOT ATFs for non-DOT tests.
§ 40.235 (c) and (d)—responsibility to follow instructions for ASDs.
§ 40.255 (b)—receipt and storage of alcohol test information.
§ 40.265 (c)–(e)—actions in ''shy lung'' situations.
§ 40.267—Cancellation of alcohol tests.
§ 40.271—Actions in ''correctable flaw'' situations in alcohol tests.
§ 40.273—Actions following cancelled tests in alcohol tests.
§ 40.275—Actions in ''non-fatal flaw'' situations in alcohol tests.
§§ 40.287–40.289—Responsibilities concerning SAP services.
§§ 40.295–40.297—Prohibition on seeking second SAP evaluation or changing SAP recommendation.
§ 40.303—Responsibilities concerning aftercare recommendations.
§ 40.305—Responsibilities concerning return-to-duty decision.
§ 40.309—Responsibilities concerning follow-up tests.
§ 40.321—General confidentiality requirement.
§ 40.323—Release of confidential information in litigation.
§ 40.331—Other circumstances for the release of confidential information.
§ 40.333—Record retention requirements.
§ 40.345—Choice of who reports drug testing information to employers.

Subpart C—Urine Collection Personnel

§ 40.31 Who may collect urine specimens for DOT drug testing?

(a) Collectors meeting the requirements of this subpart are the only persons authorized to collect urine specimens for DOT drug testing.

(b) A collector must meet training requirements of § 40.33.

(c) As the immediate supervisor of an employee being tested, you may not act as the collector when that employee is tested, unless no other collector is available and you are permitted to do so under DOT agency drug and alcohol regulations.

(d) You must not act as the collector for the employee being tested if you work for a HHS-certified laboratory (*e.g.,* as a technician or accessioner) and could link the employee with a urine specimen, drug testing result, or laboratory report.

§ 40.33 What training requirements must a collector meet?

To be permitted to act as a collector in the DOT drug testing program, you must meet each of the requirements of this section:

(a) *Basic information.* You must be knowledgeable about this part, the current ''DOT Urine Specimen Collection Procedures Guidelines,'' and DOT agency regulations applicable to the employers for whom you perform collections, and you must keep current on any changes to these materials. The DOT Urine Specimen Collection Procedures Guidelines document is available from ODAPC (Department of Transportation, 400 7th Street, SW., Room 10403, Washington DC, 20590, 202–366–3784, or on the ODAPC web site (http://www.dot.gov/ost/dapc).

(b) *Qualification training.* You must receive qualification training meeting the requirements of this paragraph. Qualification training must provide instruction on the following subjects:

(1) All steps necessary to complete a collection correctly and the proper completion and transmission of the CCF;

(2) ''Problem'' collections (*e.g.,* situations like ''shy bladder'' and attempts to tamper with a specimen);

(3) Fatal flaws, correctable flaws, and how to correct problems in collections; and

(4) The collector's responsibility for maintaining the integrity of the collection process, ensuring the privacy of employees being tested, ensuring the security of the specimen, and avoiding conduct or statements that could be viewed as offensive or inappropriate;

(c) *Initial Proficiency Demonstration.* Following your completion of qualification training under paragraph (b) of this section, you must demonstrate proficiency in collections under this part by completing five consecutive error-free mock collections.

(1) The five mock collections must include two uneventful collection scenarios, one insufficient quantity of urine scenario, one temperature out of range scenario, and one scenario in which the employee refuses to sign the CCF and initial the specimen bottle tamper-evident seal.

(2) Another person must monitor and evaluate your performance, in person or by a means that provides real-time observation and interaction between the instructor and trainee, and attest in writing that the mock collections are ''error-free.'' This person must be an individual who has demonstrated necessary knowledge, skills, and abilities by—

(i) Regularly conducting DOT drug test collections for a period of at least a year;

(ii) Conducting collector training under this part for a year; or

(iii) Successfully completing a ''train the trainer'' course.

(d) *Schedule for qualification training and initial proficiency demonstration.* The following is the schedule for qualification training and the initial proficiency demonstration you must meet:

(1) If you became a collector before August 1, 2001, and you have already met the requirements of paragraphs (b) and (c) of this section, you do not have to meet them again.

(2) If you became a collector before August 1, 2001, and have yet to meet the requirements of paragraphs (b) and (c) of this section, you must do so no later than January 31, 2003.

(3) If you become a collector on or after August 1, 2001, you must meet the requirements of paragraphs (b) and (c) of this section before you begin to perform collector functions.

(e) *Refresher training.* No less frequently than every five years from the date on which you satisfactorily complete the requirements of paragraphs (b) and (c) of this section, you must complete refresher training that meets all the requirements of paragraphs (b) and (c) of this section.

(f) *Error Correction Training.* If you make a mistake in the collection process that causes a test to be cancelled (*i.e.,* a fatal or uncorrected flaw), you must undergo error correction training. This training must occur within 30 days of the date you are notified of the error that led to the need for retraining.

(i) Error correction training must be provided and your proficiency

documented in writing by a person who meets the requirements of paragraph (c)(2) of this section.

(ii) Error correction training is required to cover only the subject matter area(s) in which the error that caused the test to be cancelled occurred.

(iii) As part of the error correction training, you must demonstrate your proficiency in the collection procedures of this part by completing three consecutive error-free mock collections. The mock collections must include one uneventful scenario and two scenarios related to the area(s) in which your error(s) occurred. The person providing the training must monitor and evaluate your performance and attest in writing that the mock collections were ''error-free.''

(g) *Documentation.* You must maintain documentation showing that you currently meet all requirements of this section. You must provide this documentation on request to DOT agency representatives and to employers and C/TPAs who are using or negotiating to use your services.

§ 40.35 What information about the DER must employers provide to collectors?

As an employer, you must provide to collectors the name and telephone number of the appropriate DER (and C/TPA, where applicable) to contact about any problems or issues that may arise during the testing process.

§ 40.37 Where is other information on the role of collectors found in this regulation?

You can find other information on the role and functions of collectors in the following sections of this part:

§ 40.3—Definition.
§ 40.43—Steps to prepare and secure collection sites.
§§ 40.45–40.47—Use of CCF.
§§ 40.49–40.51—Use of collection kit and shipping materials.
§§ 40.61–40.63—Preliminary steps in collections.
§ 40.65—Role in checking specimens.
§ 40.67—Role in directly observed collections.
§ 40.69—Role in monitored collections.
§ 40.71—Role in split specimen collections.
§ 40.73—Chain of custody completion and finishing the collection process.
§ 40.103—Processing blind specimens.
§ 40.191—Action in case of refusals to take test.
§ 40.193—Action in ''shy bladder'' situations.
§ 40.199–40.205—Collector errors in tests, effects, and means of correction.

Subpart D—Collection Sites, Forms, Equipment and Supplies Used in DOT Urine Collections

§ 40.41 Where does a urine collection for a DOT drug test take place?

(a) A urine collection for a DOT drug test must take place in a collection site meeting the requirements of this section.

(b) If you are operating a collection site, you must ensure that it meets the security requirements of § 40.43.

(c) If you are operating a collection site, you must have all necessary personnel, materials, equipment, facilities and supervision to provide for the collection, temporary storage, and shipping of urine specimens to a laboratory, and a suitable clean surface for writing.

(d) Your collection site must include a facility for urination described in either paragraph (e) or paragraph (f) of this section.

(e) The first, and preferred, type of facility for urination that a collection site may include is a single-toilet room, having a full-length privacy door, within which urination can occur.

(1) No one but the employee may be present in the room during the collection, except for the observer in the event of a directly observed collection.

(2) You must have a source of water for washing hands, that, if practicable, should be external to the closed room where urination occurs. If an external source is not available, you may meet this requirement by securing all sources of water and other substances that could be used for adulteration and substitution (*e.g.,* water faucets, soap dispensers) and providing moist towelettes outside the closed room.

(f) The second type of facility for urination that a collection site may include is a multistall restroom.

(1) Such a site must provide substantial visual privacy (*e.g.,* a toilet stall with a partial-length door) and meet all other applicable requirements of this section.

(2) If you use a multi-stall restroom, you must either—

(i) Secure all sources of water and other substances that could be used for adulteration and substitution (*e.g.*, water faucets, soap dispensers) and place bluing agent in all toilets or secure the toilets to prevent access; or

(ii) Conduct all collections in the facility as monitored collections (see § 40.69 for procedures). This is the only circumstance in which you may conduct a monitored collection.

(3) No one but the employee may be present in the multistall restroom during the collection, except for the monitor in the event of a monitored collection or the observer in the event of a directly observed collection.

(g) A collection site may be in a medical facility, a mobile facility (*e.g.*, a van), a dedicated collection facility, or any other location meeting the requirements of this section.

§ 40.43 What steps must operators of collection sites take to protect the security and integrity of urine collections?

(a) Collectors and operators of collection sites must take the steps listed in this section to prevent unauthorized access that could compromise the integrity of collections.

(b) As a collector, you must do the following before each collection to deter tampering with specimens:

(1) Secure any water sources or otherwise make them unavailable to employees (*e.g.*, turn off water inlet, tape handles to prevent opening faucets);

(2) Ensure that the water in the toilet is blue;

(3) Ensure that no soap, disinfectants, cleaning agents, or other possible adulterants are present;

(4) Inspect the site to ensure that no foreign or unauthorized substances are present;

(5) Tape or otherwise secure shut any movable toilet tank top, or put bluing in the tank;

(6) Ensure that undetected access (*e.g.*, through a door not in your view) is not possible;

(7) Secure areas and items (*e.g.*, ledges, trash receptacles, paper towel holders, under-sink areas) that appear suitable for concealing contaminants; and

(8) Recheck items in paragraphs (b)(1) through (7) of this section following each collection to ensure the site's continued integrity.

(c) If the collection site uses a facility normally used for other purposes, like a public rest room or hospital examining room, you must, as a collector, also ensure before the collection that:

(1) Access to collection materials and specimens is effectively restricted; and

(2) The facility is secured against access during the procedure to ensure privacy to the employee and prevent distraction of the collector. Limited-access signs must be posted.

(d) As a collector, you must take the following additional steps to ensure security during the collection process:

(1) To avoid distraction that could compromise security, you are limited to conducting a collection for only one employee at a time. However, during the time one employee is in the period for drinking fluids in a ''shy bladder''

situation (see § 40.193(b)), you may conduct a collection for another employee.

(2) To the greatest extent you can, keep an employee's collection container within view of both you and the employee between the time the employee has urinated and the specimen is sealed.

(3) Ensure you are the only person in addition to the employee who handles the specimen before it is poured into the bottles and sealed with tamper-evident seals.

(4) In the time between when the employee gives you the specimen and when you seal the specimen, remain within the collection site.

(5) Maintain personal control over each specimen and CCF throughout the collection process.

(e) If you are operating a collection site, you must implement a policy and procedures to prevent unauthorized personnel from entering any part of the site in which urine specimens are collected or stored.

(1) Only employees being tested, collectors and other collection site workers, DERs, employee and employer representatives authorized by the employer (*e.g.*, employer policy, collective bargaining agreement), and DOT agency representatives are authorized persons for purposes of this paragraph (e).

(2) Except for the observer in a directly observed collection or the monitor in the case of a monitored collection, you must not permit anyone to enter the urination facility in which employees provide specimens.

(3) You must ensure that all authorized persons are under the supervision of a collector at all times when permitted into the site.

(4) You or the collector may remove any person who obstructs, interferes with, or causes a delay in the collection process.

(f) If you are operating a collection site, you must minimize the number of persons handling specimens.

§ 40.45 What form is used to document a DOT urine collection?

(a) The Federal Drug Testing Custody and Control Form (CCF) must be used to document every urine collection required by the DOT drug testing program. The CCF must be a five-part carbonless manifold form. You may view this form on the Department's web site (http://www.dot.gov/ost/dapc) or the HHS web site (http://www.health.org/workpl.htm).

(b) As a participant in the DOT drug testing program, you are not permitted to modify or revise the CCF except as follows:

(1) You may include, in the area outside the border of the form, other information needed for billing or other purposes necessary to the collection process.

(2) The CCF must include the names, addresses, telephone numbers and fax numbers of the employer and the MRO, which may be preprinted, typed, or handwritten. The MRO information must include the specific physician's name and address, as opposed to only a generic clinic, health care organization, or company name. This information is required, and it is prohibited for an employer, collector, service agent or any other party to omit it. In addition, a C/TPA's name, address, fax number, and telephone number may be included, but is not required.

(3) As an employer, you may add the name of the DOT agency under whose authority the test occurred as part of the employer information.

(4) As a collector, you may use a CCF with your name, address, telephone number, and fax number preprinted, but under no circumstances may you sign the form before the collection event.

(c) Under no circumstances may the CCF transmit personal identifying information about an employee (other than a social security number (SSN) or other employee identification (ID) number) to a laboratory.

(d) As an employer, you may use an equivalent foreign-language version of the CCF approved by ODAPC. You may use such a non-English language form only in a situation where both the employee and collector understand and can use the form in that language.

§ 40.47 May employers use the CCF for non-DOT collections or non-Federal forms for DOT collections?

(a) No, as an employer, you are prohibited from using the CCF for non-DOT urine collections. You are also prohibited from using non-Federal forms for DOT urine collections. Doing either subjects you to enforcement action under DOT agency regulations.

(b) (1) In the rare case where the collector, either by mistake or as the only means to conduct a test under difficult circumstances (*e.g.*, post-accident or reasonable suspicion test with insufficient time to obtain the CCF), uses a non-Federal form for a DOT collection, the use of a non-Federal form does not present a reason for the laboratory to reject the specimen for testing or for an MRO to cancel the result.

(2) The use of the non-DOT form is a ''correctable flaw.'' As an MRO, to correct the problem you must follow the procedures of § 40.205(b)(2).

§ 40.49 What materials are used to collect urine specimens?

For each DOT drug test, you must use a collection kit meeting the requirements of Appendix A of this part.

§ 40.51 What materials are used to send urine specimens to the laboratory?

(a) Except as provided in paragraph (b) of this section, you must use a shipping container that adequately protects the specimen bottles from shipment damage in the transport of specimens from the collection site to the laboratory.

(b) You are not required to use a shipping container if a laboratory courier hand-delivers the specimens from the collection site to the laboratory.

Subpart E—Urine Specimen Collections

§ 40.61 What are the preliminary steps in the collection process?

As the collector, you must take the following steps before actually beginning a collection:

(a) When a specific time for an employee's test has been scheduled, or the collection site is at the employee's work site, and the employee does not appear at the collection site at the scheduled time, contact the DER to determine the appropriate interval within which the DER has determined the employee is authorized to arrive. If the employee's arrival is delayed beyond that time, you must notify the DER that the employee has not reported for testing. In a situation where a C/TPA has notified an owner/operator or other individual employee to report for testing and the employee does not appear, the C/TPA must notify the employee that he or she has refused to test (see § 40.191(a)(1)).

(b) Ensure that, when the employee enters the collection site, you begin the testing process without undue delay. For example, you must not wait because the employee says he or she is not ready or is unable to urinate or because an authorized employer or employee representative is delayed in arriving.

(1) If the employee is also going to take a DOT alcohol test, you must, to the greatest extent practicable, ensure that the alcohol test is completed before the urine collection process begins.

Example to Paragraph (b)(1): An employee enters the test site for both a drug and an alcohol test. Normally, the collector would wait until the BAT had completed the alcohol test process before beginning the drug test process. However, there are some situations in which an exception to this normal practice would be reasonable. One

such situation might be if several people were waiting for the BAT to conduct alcohol tests, but a drug testing collector in the same facility were free. Someone waiting might be able to complete a drug test without unduly delaying his or her alcohol test. Collectors and BATs should work together, however, to ensure that post-accident and reasonable suspicion alcohol tests happen as soon as possible (*e.g.*, by moving the employee to the head of the line for alcohol tests).

(2) If the employee needs medical attention (*e.g.,* an injured employee in an emergency medical facility who is required to have a post-accident test), do not delay this treatment to collect a specimen.

(3) You must not collect, by catheterization or other means, urine from an unconscious employee to conduct a drug test under this part. Nor may you catheterize a conscious employee. However, you must inform an employee who normally voids through self-catheterization that the employee is required to provide a specimen in that manner.

(4) If, as an employee, you normally void through self-catheterization, and decline to do so, this constitutes a refusal to test.

(c) Require the employee to provide positive identification. You must see a photo ID issued by the employer (other than in the case of an owner-operator or other self-employed individual) or a Federal, state, or local government (*e.g.,* a driver's license). You may not accept faxes or photocopies of identification. Positive identification by an employer representative (not a co-worker or another employee being tested) is also acceptable. If the employee cannot produce positive identification, you must contact a DER to verify the identity of the employee.

(d) If the employee asks, provide your identification to the employee. Your identification must include your name and your employer's name, but does not have to include your picture, address, or telephone number.

(e) Explain the basic collection procedure to the employee, including showing the employee the instructions on the back of the CCF.

(f) Direct the employee to remove outer clothing (*e.g.,* coveralls, jacket, coat, hat) that could be used to conceal items or substances that could be used to tamper with a specimen. You must also direct the employee to leave these garments and any briefcase, purse, or other personal belongings with you or in a mutually agreeable location. You must advise the employee that failure to comply with your directions constitutes a refusal to test.

(1) If the employee asks for a receipt for any belongings left with you, you must provide one.

(2) You must allow the employee to keep his or her wallet.

(3) You must not ask the employee to remove other clothing (*e.g.,* shirts, pants, dresses, underwear), to remove all clothing, or to change into a hospital or examination gown (unless the urine collection is being accomplished simultaneously with a DOT agency-authorized medical examination).

(4) You must direct the employee to empty his or her pockets and display the items in them to ensure that no items are present which could be used to adulterate the specimen. If nothing is there that can be used to adulterate a specimen, the employee can place the items back into his or her pockets. As the employee, you must allow the collector to make this observation.

(5) If, in your duties under paragraph (f)(4) of this section, you find any material that could be used to tamper with a specimen, you must:

(i) Determine if the material appears to be brought to the collection site with the intent to alter the specimen, and, if it is, conduct a directly observed collection using direct observation procedures (see § 40.67); or

(ii) Determine if the material appears to be inadvertently brought to the collection site (*e.g.,* eye drops), secure and maintain it until the collection process is completed and conduct a normal (*i.e.,* unobserved) collection.

(g) You must instruct the employee not to list medications that he or she is currently taking on the CCF. (The employee may make notes of medications on the back of the employee copy of the form for his or her own convenience, but these notes must not be transmitted to anyone else.)

§ 40.63 What steps does the collector take in the collection process before the employee provides a urine specimen?

As the collector, you must take the following steps before the employee provides the urine specimen:

(a) Complete Step 1 of the CCF.

(b) Instruct the employee to wash and dry his or her hands at this time. You must tell the employee not to wash his or her hands again until after delivering the specimen to you. You must not give the employee any further access to water or other materials that could be used to adulterate or dilute a specimen.

(c) Select, or allow the employee to select, an individually wrapped or sealed collection container from collection kit materials. Either you or the employee, with both of you present, must unwrap or break the seal of the collection container. You must not unwrap or break the seal on any specimen bottle at this time. You must not allow the employee to take anything from the collection kit into the room used for urination except the collection container.

(d) Direct the employee to go into the room used for urination, provide a specimen of at least 45 mL, not flush the toilet, and return to you with the specimen as soon as the employee has completed the void.

(1) Except in the case of an observed or a monitored collection (see §§ 40.67 and 40.69), neither you nor anyone else may go into the room with the employee.

(2) As the collector, you may set a reasonable time limit for voiding.

(e) You must pay careful attention to the employee during the entire collection process to note any conduct that clearly indicates an attempt to tamper with a specimen (*e.g.,* substitute urine in plain view or an attempt to bring into the collection site an adulterant or urine substitute). If you detect such conduct, you must require that a collection take place immediately under direct observation (see § 40.67) and note the conduct and the fact that the collection was observed in the ''Remarks'' line of the CCF (Step 2). You must also, as soon as possible, inform the DER and collection site supervisor that a collection took place under direct observation and the reason for doing so.

§ 40.65 What does the collector check for when the employee presents a specimen?

As a collector, you must check the following when the employee gives the collection container to you:

(a) *Sufficiency of specimen.* You must check to ensure that the specimen contains at least 45 mL of urine.

(1) If it does not, you must follow ''shy bladder'' procedures (see § 40.193(b)).

(2) When you follow ''shy bladder'' procedures, you must discard the original specimen, unless another problem (*i.e.,* temperature out of range, signs of tampering) also exists.

(3) You are never permitted to combine urine collected from separate voids to create a specimen.

(4) You must discard any excess urine.

(b) *Temperature.* You must check the temperature of the specimen no later than four minutes after the employee has given you the specimen.

(1) The acceptable temperature range is 32–38 °C/90–100 °F.

(2) You must determine the temperature of the specimen by reading the temperature strip attached to the collection container.

(3) If the specimen temperature is within the acceptable range, you must mark the ''Yes'' box on the CCF (Step 2).

(4) If the specimen temperature is outside the acceptable range, you must mark the ''No'' box and enter in the ''Remarks'' line (Step 2) your findings about the temperature.

(5) If the specimen temperature is outside the acceptable range, you must immediately conduct a new collection using direct observation procedures (see § 40.67).

(6) In a case where a specimen is collected under direct observation because of the temperature being out of range, you must process both the original specimen and the specimen collected using direct observation and send the two sets of specimens to the laboratory. This is true even in a case in which the original specimen has insufficient volume but the temperature is out of range. You must also, as soon as possible, inform the DER and collection site supervisor that a collection took place under direct observation and the reason for doing so.

(7) In a case where the employee refuses to provide another specimen (see § 40.191(a)(3)) or refuses to provide another specimen under direct observation (see § 40.191(a)(4)), you must notify the DER. As soon as you have notified the DER, you must discard any specimen the employee has provided previously during the collection procedure.

(c) *Signs of tampering.* You must inspect the specimen for unusual color, presence of foreign objects or material, or other signs of tampering (*e.g.,* if you notice any unusual odor).

(1) If it is apparent from this inspection that the employee has tampered with the specimen (*e.g.,* blue dye in the specimen, excessive foaming when shaken, smell of bleach), you must immediately conduct a new collection using direct observation procedures (see § 40.67).

(2) In a case where a specimen is collected under direct observation because of showing signs of tampering, you must process both the original specimen and the specimen collected using direct observation and send the two sets of specimens to the laboratory. This is true even in a case in which the original specimen has insufficient volume but it shows signs of tampering. You must also, as soon as possible, inform the DER and collection site supervisor that a collection took place under direct observation and the reason for doing so.

(3) In a case where the employee refuses to provide another specimen (see § 40.191(a)(3)) or refuses to provide a specimen under direct observation (see § 40.193(a)(4)), you must notify the DER. As soon as you have notified the DER, you must discard any specimen the employee has provided previously during the collection procedure.

§ 40.67 When and how is a directly observed collection conducted?

(a) As an employer you must direct an immediate collection under direct observation with no advance notice to the employee, if:

(1) The laboratory reported to the MRO that a specimen is invalid, and the MRO reported to you that there was not an adequate medical explanation for the result; or

(2) The MRO reported to you that the original positive, adulterated, or substituted test result had to be cancelled because the test of the split specimen could not be performed.

(b) As an employer, you may direct a collection under direct observation of an employee if the drug test is a return-to-duty test or a follow-up test.

(c) As a collector, you must immediately conduct a collection under direct observation if:

(1) You are directed by the DER to do so (see paragraphs (a) and (c) of this section); or

(2) You observed materials brought to the collection site or the employee's conduct clearly indicates an attempt to tamper with a specimen (see §§ 40.61(f)(5)(i) and 40.63(e)); or

(3) The temperature on the original specimen was out of range (see § 40.65(b)(5)); or (4) The original specimen appeared to have been tampered with (see § 40.65(c)(1)).

(d)(1) As the employer, you must explain to the employee the reason for a directly observed collection under paragraph (a) or (b) of this section.

(2) As the collector, you must explain to the employee the reason under this part for a directly observed collection under paragraphs (c)(2) through (4) of this section.

(e) As the collector, you must complete a new CCF for the directly observed collection.

(1) You must mark the ''reason for test'' block (Step 1) the same as for the first collection.

(2) You must check the ''Observed, (Enter Remark)'' box and enter the reason (see § 40.67(b)) in the ''Remarks'' line (Step 2).

(f) In a case where two sets of specimens are being sent to the laboratory because of suspected tampering with the specimen at the collection site, enter on the ''Remarks'' line of the CCF (Step 2) for each specimen a notation to this effect (*e.g.,* collection 1 of 2, or 2 of 2) and the specimen ID number of the other specimen.

(g) As the collector, you must ensure that the observer is the same gender as the employee. You must never permit an opposite gender person to act as the observer. The observer can be a different person from the collector and need not be a qualified collector.

(h) As the collector, if someone else is to observe the collection (*e.g.,* in order to ensure a same gender observer), you must verbally instruct that person to follow procedures at paragraphs (i) and (j) of this section. If you, the collector, are the observer, you too must follow these procedures.

(i) As the observer, you must watch the employee urinate into the collection container. Specifically, you are to watch the urine go from the employee's body into the collection container.

(j) As the observer but not the collector, you must not take the collection container from the employee, but you must observe the specimen as the employee takes it to the collector.

(k) As the collector, when someone else has acted as the observer, you must include the observer's name in the ''Remarks'' line of the CCF (Step 2).

(l) As the employee, if you decline to allow a directly observed collection required or permitted under this section to occur, this is a refusal to test.

§ 40.69 How is a monitored collection conducted?

(a) As the collector, you must secure the room being used for the monitored collection so that no one except the employee and the monitor can enter it until after the collection has been completed.

(b) As the collector, you must ensure that the monitor is the same gender as the employee, unless the monitor is a medical professional (*e.g.,* nurse, doctor, physician's assistant). The monitor can be a different person from the collector and need not be a qualified collector.

(c) As the collector, if someone else is to monitor the collection (*e.g.,* in order to ensure a same gender monitor), you must verbally instruct that person to follow procedures at paragraphs (d) and (e) of this section. If you, the collector, are the observer, you too must follow these procedures.

(d) As the monitor, you must not watch the employee urinate into the collection container. If you hear sounds or make other observations indicating an attempt to tamper with a specimen, there must be an additional collection under direct observation (see §§ 40.63(e), 40.65(c), and 40.67(b)).

(e) As the monitor, you must ensure that the employee takes the collection container directly to the collector as soon as the employee has exited the enclosure.

(f) As the collector, when someone else has acted as the monitor, you must note that person's name in the ''Remarks'' line of the CCF (Step 2).

(g) As the employee being tested, if you decline to permit a collection authorized under this section to be monitored, it is a refusal to test.

§ 40.71 How does the collector prepare the specimens?

(a) All collections under DOT agency drug testing regulations must be split specimen collections.

(b) As the collector, you must take the following steps, in order, after the employee brings the urine specimen to you. You must take these steps in the presence of the employee.

(1) Check the box on the CCF (Step 2) indicating that this was a split specimen collection.

(2) You, not the employee, must first pour at least 30 mL of urine from the collection container into one specimen bottle, to be used for the primary specimen.

(3) You, not the employee, must then pour at least 15 mL of urine from the collection container into the second specimen bottle to be used for the split specimen.

(4) You, not the employee, must place and secure (*i.e.,* tighten or snap) the lids/caps on the bottles.

(5) You, not the employee, must seal the bottles by placing the tamper-evident bottle seals over the bottle caps/lids and down the sides of the bottles.

(6) You, not the employee, must then write the date on the tamper-evident bottle seals.

(7) You must then ensure that the employee initials the tamper-evident bottle seals for the purpose of certifying that the bottles contain the specimens he or she provided. If the employee fails or refuses to do so, you must note this in the ''Remarks'' line of the CCF (Step 2) and complete the collection process.

§ 40.73 How is the collection process completed?

(a) As the collector, you must do the following things to complete the collection process. You must complete the steps called for in paragraphs (a)(1) through (a)(7) of this section in the employee's presence.

(1) Direct the employee to read and sign the certification statement on Copy 2 (Step 5) of the CCF and provide date of birth, printed name, and day and evening contact telephone numbers. If the employee refuses to sign the CCF or to provide date of birth, printed name, or telephone numbers, you must note this in the ''Remarks'' line (Step 2) of the CCF, and complete the collection. If the employee refuses to fill out any information, you must, as a minimum, print the employee's name in the appropriate place.

(2) Complete the chain of custody on the CCF (Step 5) by printing your name (note: you may pre-print your name), recording the time and date of the collection, signing the statement, and entering the name of the delivery service transferring the specimen to the laboratory,

(3) Ensure that all copies of the CCF are legible and complete.

(4) Remove Copy 5 of the CCF and give it to the employee.

(5) Place the specimen bottles and Copy 1 of the CCF in the appropriate pouches of the plastic bag.

(6) Secure both pouches of the plastic bag.

(7) Advise the employee that he or she may leave the collection site.

(8) To prepare the sealed plastic bag containing the specimens and CCF for shipment you must:

(i) Place the sealed plastic bag in a shipping container (*e.g.,* standard courier box) designed to minimize the possibility of damage during shipment. (More than one sealed plastic bag can be placed into a single shipping container if you are doing multiple collections.)

(ii) Seal the container as appropriate.

(iii) If a laboratory courier hand-delivers the specimens from the collection site to the laboratory, prepare the sealed plastic bag for shipment as directed by the courier service.

(9) Send Copy 2 of the CCF to the MRO and Copy 4 to the DER. You must fax or otherwise transmit these copies to the MRO and DER within 24 hours or during the next business day. Keep Copy 3 for at least 30 days, unless otherwise specified by applicable DOT agency regulations.

(b) As a collector or collection site, you must ensure that each specimen you collect is shipped to a laboratory as quickly as possible, but in any case within 24 hours or during the next business day.

Subpart F—Drug Testing Laboratories

§ 40.81 What laboratories may be used for DOT drug testing?

(a) As a drug testing laboratory located in the U.S., you are permitted to participate in DOT drug testing only if you are certified by HHS under the National Laboratory Certification Program (NLCP) for all testing required under this part.

(b) As a drug testing laboratory located in Canada or Mexico which is not certified by HHS under the NLCP, you are permitted to participate in DOT drug testing only if:

(1) The DOT, based on a written recommendation from HHS, has approved your laboratory as meeting HHS laboratory certification standards or deemed your laboratory fully equivalent to a laboratory meeting HHS laboratory certification standards for all testing required under this part; or

(2) The DOT, based on a written recommendation from HHS, has recognized a Canadian or Mexican certifying organization as having equivalent laboratory certification standards and procedures to those of HHS, and the Canadian or Mexican certifying organization has certified your laboratory under those equivalent standards and procedures.

(c) As a laboratory participating in the DOT drug testing program, you must comply with the requirements of this part. You must also comply with all applicable requirements of HHS in testing DOT specimens, whether or not the HHS requirements are explicitly stated in this part.

(d) If DOT determines that you are in noncompliance with this part, you could be subject to PIE proceedings under Subpart R of this part. If the Department issues a PIE with respect to you, you are ineligible to participate in the DOT drug testing program even if you continue to meet the requirements of paragraph (a) or (b) of this section.

§ 40.83 How do laboratories process incoming specimens?

As the laboratory, you must do the following when you receive a DOT specimen:

(a) You are authorized to receive only the laboratory copy of the CCF. You are not authorized to receive other copies of the CCF nor any copies of the alcohol testing form.

(b) You must comply with applicable provisions of the HHS Guidelines concerning accessioning and processing urine drug specimens.

(c) You must inspect each specimen and CCF for the following ''fatal flaws:''

(1) The specimen ID numbers on the specimen bottle and the CCF do not match;

(2) The specimen bottle seal is broken or shows evidence of tampering, unless a split specimen can be redesignated (see paragraph (g) of this section);

(3) The collector's printed name *and* signature are omitted from the CCF; and

(4) There is an insufficient amount of urine in the primary bottle for analysis, unless the specimens can be

redesignated (see paragraph (g) of this section).

(d) When you find a specimen meeting the criteria of paragraph (c) of this section, you must document your findings and stop the testing process. Report the result in accordance with § 40.97(a)(3) .

(e) You must inspect each specimen and CCF for the following ''correctable flaws'':

(1) The specimen temperature was not checked and the ''Remarks'' line did not contain an entry regarding the temperature being outside of range; and

(2) The collector's signature is omitted on the certification statement on the CCF.

(f) Upon finding that a specimen meets the criteria of paragraph (e) of this section, document the flaw and continue the testing process.

(1) In such a case, you must retain the specimen for a minimum of 5 business days from the date on which you initiated action to correct the flaw.

(2) You must then attempt to correct the flaw by following the procedures of § 40.205(b).

(3) If the flaw is not corrected, report the result in accordance with § 40.97(a)(3).

(g) If the CCF is marked indicating that a split specimen collection was collected and if the split specimen does not accompany the primary, has leaked, or is otherwise unavailable for testing, you must still test the primary specimen and follow appropriate procedures outlined in § 40.175(b) regarding the unavailability of the split specimen for testing.

(1) The primary specimen and the split specimen can be redesignated (*i.e.,* Bottle B is redesignated as Bottle A, and vice-versa) if:

(i) The primary specimen appears to have leaked out of its sealed bottle and the laboratory believes a sufficient amount of urine exists in the split specimen to conduct all appropriate primary laboratory testing; or

(ii) The primary specimen is labeled as Bottle B, and the split specimen as Bottle A; or

(iii) The laboratory opens the split specimen instead of the primary specimen, the primary specimen remains sealed, and the laboratory believes a sufficient amount of urine exists in the split specimen to conduct all appropriate primary laboratory testing; or

(iv) The primary specimen seal is broken but the split specimen remains sealed and the laboratory believes a sufficient amount of urine exists in the split specimen to conduct all appropriate primary laboratory testing.

(2) In situations outlined in paragraph (g)(1) of this section, the laboratory shall mark through the ''A'' and write ''B,'' then initial and date the change. A corresponding change shall be made to the other bottle by marking through the ''B'' and writing ''A,'' and initialing and dating the change.

(h) A notation shall be made on Copy 1 of the CCF (Step 5a) and on any laboratory internal chain of custody documents, as appropriate, for any fatal or correctable flaw.

§ 40.85 What drugs do laboratories test for?

As a laboratory, you must test for the following five drugs or classes of drugs in a DOT drug test. You must not test ''DOT specimens'' for any other drugs.

(a) Marijuana metabolites.

(b) Cocaine metabolites.

(c) Amphetamines.

(d) Opiate metabolites.

(e) Phencyclidine (PCP).

§ 40.87 What are the cutoff concentrations for initial and confirmation tests?

(a) As a laboratory, you must use the cutoff concentrations displayed in the following table for initial and confirmation drug tests. All cutoff concentrations are expressed in nanograms per milliliter (ng/mL). The table follows:

Type of drug or metabolite	Initial test	Confirmation test
(1) Marijuana metabolites	50	
(i) Delta-9-tetrahydrocanna-binol-9-carboxylic acid (THC)		15
(2) Cocaine metabolites (Benzoylecgonine)	300	150
(3) Phencyclidine (PCP)	25	25
(4) Amphetamines	1000	
(i) Amphetamine		500
(ii) Methamphetamine		500 (Specimen must also contain amphetamine at a concentration of greater than or equal to 200 ng/mL.)
(5) Opiate metabolites	2000	
(i) Codeine		2000
(ii) Morphine		2000
(iii) 6-acetylmorphine (6–AM)		10 (Test for 6–AM in the specimen. Conduct this test only when specimen contains morphine at a concentration greater than or equal to 2000 ng/mL.)

(b) On an initial drug test, you must report a result below the cutoff concentration as negative. If the result is at or above the cutoff concentration, you must conduct a confirmation test.

(c) On a confirmation drug test, you must report a result below the cutoff concentration as negative and a result at or above the cutoff concentration as confirmed positive.

(d) You must report quantitative values for morphine or codeine at 15,000 ng/mL or above.

§ 40.89 What is validity testing, and are laboratories required to conduct it?

(a) Specimen validity testing is the evaluation of the specimen to determine if it is consistent with normal human urine. The purpose of validity testing is to determine whether certain adulterants or foreign substances were added to the urine, if the urine was diluted, or if the specimen was substituted.

(b) As a laboratory, you must conduct validity testing.

§ 40.91 What validity tests must laboratories conduct on primary specimens?

As a laboratory, when you conduct validity testing under § 40.89, you must conduct it in accordance with the requirements of this section.

(a) You must test each primary specimen for creatinine. You must also determine its specific gravity if you find that the creatinine concentration is less than 20 mg/dL.

(b) You must measure the pH of each primary specimen.

(c) You must test each primary specimen to determine if it contains

substances that may be used to adulterate the specimen. Your tests must have the capability of determining whether any substance identified in current HHS requirements or specimen validity guidance is present in the specimen.

(d) If you suspect the presence of an interfering substance/adulterant that could make a test result invalid, but you are unable to identify it (*e.g.,* a new adulterant), you must, as the first laboratory, send the specimen to another HHS certified laboratory that has the capability of doing so.

(e) If you identify a substance in a specimen that appears to be an adulterant, but which is not listed in current HHS requirements or guidance, you must report the finding in writing to ODAPC and the Division of Workplace Programs, HHS, within three business days. You must also complete testing of the specimen for drugs, to the extent technically feasible.

(f) You must conserve as much as possible of the specimen for possible future testing.

§ 40.93 What criteria do laboratories use to establish that a specimen is dilute or substituted?

(a) As a laboratory you must consider the primary specimen to be dilute if the creatinine concentration is less than 20 mg/dL and the specific gravity is less than 1.003, unless the criteria for a substituted specimen are met.

(b) As a laboratory you must consider the primary specimen to be substituted if the creatinine concentration is less than or equal to 5 mg/dL *and* the specific gravity is less than or equal to 1.001 or greater than or equal to 1.020.

§ 40.95 What criteria do laboratories use to establish that a specimen is adulterated?

(a) As a laboratory, you must consider the primary specimen to be adulterated if you determine that—

(1) A substance that is not expected to be present in human urine is identified in the specimen;

(2) A substance that is expected to be present in human urine is identified at a concentration so high that it is not consistent with human urine; or

(3) The physical characteristics of the specimen are outside the normal expected range for human urine.

(b) In making your determination under paragraph (a) of this section, you must apply the criteria in current HHS requirements or specimen validity guidance.

§ 40.97 What do laboratories report and how do they report it?

(a) As a laboratory, you must report the results for each primary specimen tested as one of the following:

(1) Negative;

(2) Negative—dilute;

(3) Rejected for testing, with remark(s);

(4) Positive, with drug(s)/metabolite(s) noted;

(5) Positive, with drug(s)/metabolite(s) noted—dilute;

(6) Adulterated, with remark(s);

(7) Substituted, with remark(s); or

(8) Invalid result, with remark(s).

(b) As a laboratory, you must report laboratory results directly, and only, to the MRO at his or her place of business. You must not report results to or through the DER or a service agent (*e.g.,* C/TPA).

(1) Negative results: You must fax, courier, mail, or electronically transmit a legible image or copy of the fully-completed Copy 1 of the CCF which has been signed by the certifying scientist, or you may provide the laboratory results report electronically (*i.e.,* computer data file).

(i) If you elect to provide the laboratory results report, you must include the following elements, as a minimum, in the report format:

(A) Laboratory name;

(B) Employer's name (you may include I.D. or account number;

(C) Specimen I.D. number;

(D) Donor's SSN or employee I.D. number, if provided; '

(E) Reason for test, if provided;

(F) Date of the collection;

(G) Date received at the laboratory;

(H) Date certifying scientist released the results;

(I) Results (*e.g.,* positive, adulterated) as listed in paragraph (a) of this section; and

(J) Remarks section, with an explanation of any situation in which a correctable flaw has been corrected.

(ii) The laboratory results report may be released only after review and approval by the certifying scientist and must reflect the same test result information as contained on the CCF signed by the certifying scientist.

(iii) The results report may be transmitted through any means that ensures accuracy and confidentiality. You, as the laboratory, together with the MRO, must ensure that the information is adequately protected from unauthorized access or release, both during transmission and in storage.

(2) Non-negative results: You must fax, courier, mail, or electronically transmit a legible image or copy of the fully-completed Copy 1 of the CCF that has been signed by the certifying scientist. In addition, you may provide the electronic laboratory results report following the format and procedures set forth in paragraphs (b)(1)(i) and (ii) of this section.

(c) In transmitting laboratory results to the MRO, you, as the laboratory, together with the MRO, must ensure that the information is adequately protected from unauthorized access or release, both during transmission and in storage. If the results are provided by fax, the fax connection must have a fixed telephone number accessible only to authorized individuals.

(d) You must transmit test results to the MRO in a timely manner, preferably the same day that review by the certifying scientist is completed.

(e) You must provide quantitative values for confirmed positive drug, adulterated, and substituted test results to the MRO when the MRO requests you to do so in writing. The MRO's request may either be a general request covering all such results you send to the MRO or a specific case-by-case request.

(f) You must provide quantitative values for confirmed opiate results for morphine or codeine at 15,000 ng/mL or above, even if the MRO has not requested quantitative values for the test result.

§ 40.99 How long does the laboratory retain specimens after testing?

(a) As a laboratory testing the primary specimen, you must retain a specimen that was reported with positive, adulterated, substituted, or invalid results for a minimum of one year.

(b) You must keep such a specimen in secure, long-term, frozen storage in accordance with HHS requirements.

(c) Within the one-year period, the MRO, the employee, the employer, or a DOT agency may request in writing that you retain a specimen for an additional period of time (*e.g.,* for the purpose of preserving evidence for litigation or a safety investigation). If you receive such a request, you must comply with it. If you do not receive such a request, you may discard the specimen at the end of the year.

(d) If you have not sent the split specimen to another laboratory for testing, you must retain the split specimen for an employee's test for the same period of time that you retain the primary specimen and under the same storage conditions.

(e) As the laboratory testing the split specimen, you must meet the requirements of paragraphs (a) through (d) of this section with respect to the split specimen.

§ 40.101 What relationship may a laboratory have with an MRO?

(a) As a laboratory, you may not enter into any relationship with an MRO that creates a conflict of interest or the appearance of a conflict of interest with the MRO's responsibilities for the employer. You may not derive any financial benefit by having an employer use a specific MRO.

(b) The following are examples of relationships between laboratories and MROs that the Department regards as creating conflicts of interest, or the appearance of such conflicts. This following list of examples is not intended to be exclusive or exhaustive:

(1) The laboratory employs an MRO who reviews test results produced by the laboratory;

(2) The laboratory has a contract or retainer with the MRO for the review of test results produced by the laboratory;

(3) The laboratory designates which MRO the employer is to use, gives the employer a slate of MROs from which to choose, or recommends certain MROs;

(4) The laboratory gives the employer a discount or other incentive to use a particular MRO;

(5) The laboratory has its place of business co-located with that of an MRO or MRO staff who review test results produced by the laboratory; or

(6) The laboratory permits an MRO, or an MRO's organization, to have a financial interest in the laboratory.

§ 40.103 What are the requirements for submitting blind specimens to a laboratory?

(a) As an employer or C/TPA with an aggregate of 2000 or more DOT-covered employees, you must send blind specimens to laboratories you use. If you have an aggregate of fewer than 2000 DOT-covered employees, you are not required to provide blind specimens.

(b) To each laboratory to which you send at least 100 specimens in a year, you must transmit a number of blind specimens equivalent to one percent of the specimens you send to that laboratory, up to a maximum of 50 blind specimens in each quarter (*i.e.,* January–March, April–June, July–September, October–December). As a C/TPA, you must apply this percentage to the total number of DOT-covered employees' specimens you send to the laboratory. Your blind specimen submissions must be evenly spread throughout the year. The following examples illustrate how this requirement works:

Example 1 to Paragraph (b). You send 2500 specimens to Lab X in Year 1. In this case, you would send 25 blind specimens to Lab X in Year 1. To meet the even distribution requirement, you would send 6 in each of three quarters and 7 in the other.

Example 2 to Paragraph (b). You send 2000 specimens to Lab X and 1000 specimens to Lab Y in Year 1. In this case, you would send 20 blind specimens to Lab X and 10 to Lab Y in Year 1. The even distribution requirement would apply in a similar way to that described in Example 1.

Example 3 to Paragraph (b). Same as Example 2, except that you also send 20 specimens to Lab Z. In this case, you would send blind specimens to Labs X and Y as in Example 2. You would not have to send any blind specimens to Lab Z, because you sent fewer than 100 specimens to Lab Z.

Example 4 to Paragraph (b). You are a C/TPA sending 2000 specimens to Lab X in Year 1. These 2000 specimens represent 200 small employers who have an average of 10 covered employees each. In this case you—not the individual employers—send 20 blind specimens to Lab X in Year 1, again ensuring even distribution. The individual employers you represent are not required to provide any blind specimens on their own.

Example 5 to Paragraph (b). You are a large C/TPA that sends 40,000 specimens to Lab Y in Year 1. One percent of that figure is 400. However, the 50 blind specimen per quarter ''cap'' means that you need send only 50 blind specimens per quarter, rather than the 100 per quarter you would have to send to meet the one percent rate. Your annual total would be 200, rather than 400, blind specimens.

(c) Approximately 75 percent of the specimens you submit must be blank (*i.e.,* containing no drugs, nor adulterated or substituted). Approximately 15 percent must be positive for one or more of the five drugs involved in DOT tests, and approximately 10 percent must either be adulterated with a substance cited in HHS guidance or substituted (*i.e.,* having specific gravity and creatinine meeting the criteria of § 40.93(b)).

(1) The blind specimens that you submit that contain drugs, that are adulterated with a substance cited in HHS guidance, or that are substituted must be validated as to their contents by the supplier using initial and confirmatory tests.

(2) The supplier must provide information regarding the shelf life of the blind specimens.

(3) If the blind specimen is drug positive, the concentration of drug it contains must be between 1.5 and 2 times the initial drug test cutoff concentration.

(4) If the blind specimen is adulterated with nitrite, the concentration of nitrite it contains must be between 1.5 and 2 times the initial validity test cutoff concentration.

(5) If the blind specimen is adulterated by altering pH, the pH must be less than or equal to 2, or greater than or equal to 12.

(6) If the blind specimen is substituted, the creatinine must be less than or equal to 2, and the specific gravity must be 1.000.

(d) You must ensure that each blind specimen is indistinguishable to the laboratory from a normal specimen.

(1) You must submit blind specimens to the laboratory using the same channels (*e.g.,* via a regular collection site) through which employees' specimens are sent to the laboratory.

(2) You must ensure that the collector uses a CCF, places fictional initials on the specimen bottle label/seal, indicates for the MRO on Copy 2 that the specimen is a blind specimen, and discards Copies 4 and 5 (employer and employee copies).

(3) You must ensure that all blind specimens include split specimens.

§ 40.105 What happens if the laboratory reports a result different from that expected for a blind specimen?

(a) If you are an employer, MRO, or C/TPA who submits a blind specimen, and if the result reported to the MRO is different from the result expected, you must investigate the discrepancy.

(b) If the unexpected result is a false negative, you must provide the laboratory with the expected results (obtained from the supplier of the blind specimen), and direct the laboratory to determine the reason for the discrepancy.

(c) If the unexpected result is a false positive, you must provide the laboratory with the expected results (obtained from the supplier of the blind specimen), and direct the laboratory to determine the reason for the discrepancy. You must also notify ODAPC of the discrepancy by telephone (202–366–3784) or e-mail (addresses are listed on the ODAPC web site, http://www.dot.gov/ost/dapc). ODAPC will notify HHS who will take appropriate action.

§ 40.107 Who may inspect laboratories?

As a laboratory, you must permit an inspection, with or without prior notice, by ODAPC, a DOT agency, or a DOT-regulated employer that contracts with the laboratory for drug testing under the DOT drug testing program, or the designee of such an employer.

§ 40.109 What documentation must the laboratory keep, and for how long?

(a) As a laboratory, you must retain all records pertaining to each employee urine specimen for a minimum of two years.

(b) As a laboratory, you must also keep for two years employer-specific data required in § 40.111.

(c) Within the two-year period, the MRO, the employee, the employer, or a DOT agency may request in writing that you retain the records for an additional period of time (*e.g.,* for the purpose of preserving evidence for litigation or a safety investigation). If you receive such a request, you must comply with it. If you do not receive such a request, you may discard the records at the end of the two-year period.

§ 40.111 When and how must a laboratory disclose statistical summaries and other information it maintains?

(a) As a laboratory, you must transmit an aggregate statistical summary, by employer, of the data listed in Appendix B to this part to the employer on a semi-annual basis.

(1) The summary must not reveal the identity of any employee.

(2) In order to avoid sending data from which it is likely that information about an employee's test result can be readily inferred, you must not send a summary if the employer has fewer than five aggregate tests results.

(3) The summary must be sent by January 20 of each year for July 1 through December 31 of the prior year.

(4) The summary must also be sent by July 20 of each year for January 1 through June 30 of the current year.

(b) When the employer requests a summary in response to an inspection, audit, or review by a DOT agency, you must provide it unless the employer had fewer than five aggregate test results. In that case, you must send the employer a report indicating that not enough testing was conducted to warrant a summary. You may transmit the summary or report by hard copy, fax, or other electronic means.

(c) You must also release information to appropriate parties as provided in §§ 40.329 and 40.331.

§ 40.113 Where is other information concerning laboratories found in this regulation?

You can find more information concerning laboratories in several sections of this part:

§ 40.3—Definition.
§ 40.13—Prohibition on making specimens available for other purposes.
§ 40.31—Conflicts of interest concerning collectors.
§ 40.47—Laboratory rejections of test for improper form.
§ 40.125—Conflicts of interest concerning MROs.
§ 40.175—Role of first laboratory in split specimen tests.
§ 40.177—Role of second laboratory in split specimen tests (drugs).
§ 40.179—Role of second laboratory in split specimen tests (adulterants).
§ 40.181—Role of second laboratory in split specimen tests (substitution).
§§ 40.183–40.185—Transmission of split specimen test results to MRO.
§§ 40.201–40.205—Role in correcting errors.
§ 40.329—Release of information to employees.
§ 40.331—Limits on release of information.
§ 40.355—Role with respect to other service agents.

Subpart G—Medical Review Officers and the Verification Process

§ 40.121 Who is qualified to act as an MRO?

To be qualified to act as an MRO in the DOT drug testing program, you must meet each of the requirements of this section:

(a) *Credentials.* You must be a licensed physician (Doctor of Medicine or Osteopathy). If you are a licensed physician in any U.S., Canadian, or Mexican jurisdiction and meet the other requirements of this section, you are authorized to perform MRO services with respect to all covered employees, wherever they are located. For example, if you are licensed as an M.D. in one state or province in the U.S., Canada, or Mexico, you are not limited to performing MRO functions in that state or province, and you may perform MRO functions for employees in other states or provinces without becoming licensed to practice medicine in the other jurisdictions.

(b) *Basic knowledge.* You must be knowledgeable in the following areas:

(1) You must be knowledgeable about and have clinical experience in controlled substances abuse disorders, including detailed knowledge of alternative medical explanations for laboratory confirmed drug test results.

(2) You must be knowledgeable about issues relating to adulterated and substituted specimens as well as the possible medical causes of specimens having an invalid result.

(3) You must be knowledgeable about this part, the DOT MRO Guidelines, and the DOT agency regulations applicable to the employers for whom you evaluate drug test results, and you must keep current on any changes to these materials. The DOT MRO Guidelines document is available from ODAPC (Department of Transportation, 400 7th Street, SW., Room 10403, Washington, DC 20590, 202–366–3784, or on the ODAPC web site (http://*www.dot.gov/ost/dapc*)).

(c) *Qualification training.* You must receive qualification training meeting the requirements of this paragraph (c).

(1) Qualification training must provide instruction on the following subjects:

(i) Collection procedures for urine specimens;

(ii) Chain of custody, reporting, and recordkeeping;

(iii) Interpretation of drug and validity tests results;

(iv) The role and responsibilities of the MRO in the DOT drug testing program;

(v) The interaction with other participants in the program (*e.g.,* DERs, SAPs); and

(vi) Provisions of this part and DOT agency rules applying to employers for whom you review test results, including changes and updates to this part and DOT agency rules, guidance, interpretations, and policies affecting the performance of MRO functions, as well as issues that MROs confront in carrying out their duties under this part and DOT agency rules.

(2) Following your completion of qualification training under paragraph (c)(1) of this section, you must satisfactorily complete an examination administered by a nationally-recognized MRO certification board or subspecialty board for medical practitioners in the field of medical review of DOT-mandated drug tests. The examination must comprehensively cover all the elements of qualification training listed in paragraph (c)(1) of this section.

(3) The following is the schedule for qualification training you must meet:

(i) If you became an MRO before August 1, 2001, and have already met the qualification training requirement, you do not have to meet it again.

(ii) If you became an MRO before August 1, 2001, but have not yet met the qualification training requirement, you must do so no later than January 31, 2003.

(iii) If you become an MRO on or after August 1, 2001, you must meet the qualification training requirement before you begin to perform MRO functions.

(d) *Continuing Education.* During each three-year period from the date on which you satisfactorily complete the examination under paragraph (c)(2) of this section, you must complete continuing education consisting of at least 12 professional development hours (*e.g.,* Continuing Education Medical Units) relevant to performing MRO functions.

(1) This continuing education must include material concerning new technologies, interpretations, recent guidance, rule changes, and other information about developments in MRO practice, pertaining to the DOT program, since the time you met the qualification training requirements of this section.

(2) Your continuing education activities must include assessment tools to assist you in determining whether you have adequately learned the material.

(e) *Documentation.* You must maintain documentation showing that you currently meet all requirements of this section. You must provide this documentation on request to DOT agency representatives and to employers and C/TPAs who are using or negotiating to use your services.

§ 40.123 What are the MRO's responsibilities in the DOT drug testing program?

As an MRO, you have the following basic responsibilities:

(a) Acting as an independent and impartial ''gatekeeper'' and advocate for the accuracy and integrity of the drug testing process.

(b) Providing a quality assurance review of the drug testing process for the specimens under your purview. This includes, but is not limited to:

(1) Ensuring the review of the CCF on all specimen collections for the purposes of determining whether there is a problem that may cause a test to be cancelled (see §§ 40.199–40.203). As an MRO, you are not required to review laboratory internal chain of custody documentation. No one is permitted to cancel a test because you have not reviewed this documentation;

(2) Providing feedback to employers, collection sites and laboratories regarding performance issues where necessary; and

(3) Reporting to and consulting with the ODAPC or a relevant DOT agency when you wish DOT assistance in resolving any program issue. As an employer or service agent, you are prohibited from limiting or attempting to limit the MRO's access to DOT for this purpose and from retaliating in any way against an MRO for discussing drug testing issues with DOT.

(c) You must determine whether there is a legitimate medical explanation for confirmed positive, adulterated, substituted, and invalid drug tests results from the laboratory.

(d) While you provide medical review of employees' test results, this part does not deem that you have established a doctor-patient relationship with the employees whose tests you review.

(e) You must act to investigate and correct problems where possible and notify appropriate parties (*e.g.,* HHS, DOT, employers, service agents) where assistance is needed, (*e.g.,* cancelled or problematic tests, incorrect results, problems with blind specimens).

(f) You must ensure the timely flow of test results and other information to employers.

(g) You must protect the confidentiality of the drug testing information.

(h) You must perform all your functions in compliance with this part and other DOT agency regulations.

§ 40.125 What relationship may an MRO have with a laboratory?

As an MRO, you may not enter into any relationship with an employer's laboratory that creates a conflict of interest or the appearance of a conflict of interest with your responsibilities to that employer. You may not derive any financial benefit by having an employer use a specific laboratory. For examples of relationships between laboratories and MROs that the Department views as creating a conflict of interest or the appearance of such a conflict, see § 40.101(b).

§ 40.127 What are the MRO's functions in reviewing negative test results?

As the MRO, you must do the following with respect to negative drug test results you receive from a laboratory, prior to verifying the result and releasing it to the DER:

(a) Review Copy 2 of the CCF to determine if there are any fatal or correctable errors that may require you to initiate corrective action or to cancel the test (see §§ 40.199 and 40.203).

(b) Review the negative laboratory test result and ensure that it is consistent with the information contained on the CCF.

(c) Before you report a negative test result, you must have in your possession the following documents:

(1) Copy 2 of the CCF, a legible copy of it, or any other CCF copy containing the employee's signature; and

(2) A legible copy (fax, photocopy, image) of Copy 1 of the CCF or the electronic laboratory results report that conveys the negative laboratory test result.

(d) If the copy of the documentation provided to you by the collector or laboratory appears unclear, you must request that the collector or laboratory send you a legible copy.

(e) On Copy 2 of the CCF, place a check mark in the ''Negative'' box (Step 6), provide your name, and sign, initial, or stamp and date the verification statement.

(f) Report the result in a confidential manner (see §§ 40.163–40.167).

(g) Staff under your direct, personal supervision may the administrative functions of this section for you, but only you can cancel a test.

(1) On specimen results that are reviewed by your staff, you are responsible for assuring the quality of their work.

(2) You are required to personally review at least 5 percent of all CCFs reviewed by your staff on a quarterly basis, including all results that required a corrective action. However, you need not review more than 500 negative results in any quarter.

(3) Your review must, as a minimum, include the CCF, negative laboratory test result, any accompanying corrective documents, and the report sent to the employer. You must correct any errors that you discover. You must take action as necessary to ensure compliance by your staff with this part and document your corrective action. You must attest to the quality assurance review by initialing the CCFs that you review.

(4) You must make these CCFs easily identifiable and retrievable by you for review by DOT agencies.

§ 40.129 What are the MRO's functions in reviewing laboratory confirmed positive, adulterated, substituted, or invalid drug test results?

(a) As the MRO, you must do the following with respect to confirmed positive, adulterated, substituted, or invalid drug tests you receive from a laboratory, before you verify the result and release it to the DER:

(1) Review Copy 2 of the CCF to determine if there are any fatal or correctable errors that may require you to cancel the test (see §§ 40.199 and 40.203). Staff under your direct, personal supervision may conduct this administrative review for you, but only you may verify or cancel a test.

(2) Review Copy 1 of the CCF and ensure that it is consistent with the information contained on Copy 2, that the test result is legible, and that the certifying scientist signed the form. You are not required to review any other documentation generated by the laboratory during their analysis or handling of the specimen (*e.g.,* the laboratory internal chain of custody).

(3) If the copy of the documentation provided to you by the collector or laboratory appears unclear, you must request that the collector or laboratory send you a legible copy.

(4) Except in the circumstances spelled out in § 40.133 , conduct a verification interview. This interview must include direct contact in person or by telephone between you and the employee. You may initiate the verification process based on the laboratory results report.

(5) Verify the test result as either negative, positive, test cancelled, or

refusal to test because of adulteration or substitution, consistent with the requirements of §§ 40.135–40.145 and 40.159 .

(b) Before you report a verified negative, positive, test cancelled, refusal to test because of adulteration or substitution, you must have in your possession the following documents:

(1) Copy 2 of the CCF, a legible copy of it, or any other CCF copy containing the employee's signature; and

(2) A legible copy (fax, photocopy, image) of Copy 1 of the CCF, containing the certifying scientist's signature.

(c) With respect to verified positive test results, place a check mark in the ''Positive'' box (Step 6) on Copy 2 of the CCF, indicate the drug(s)/ metabolite(s) detected on the ''Remarks'' line, sign and date the verification statement.

(d) Report the result in a confidential manner (see §§ 40.163–40.167).

(e) With respect to adulteration or substitution test results, check the ''refusal to test because:'' box (Step 6) on Copy 2 of the CCF, check the ''Adulterated'' or ''Substituted'' box, as appropriate, make appropriate annotation in the ''Remarks'' line, sign and date the verification statement.

(f) As the MRO, your actions concerning reporting confirmed positive, adulterated, or substituted results to the employer before you have completed the verification process are also governed by the stand-down provisions of § 40.21 .

(1) If an employer has a stand-down policy that meets the requirements of § 40.21 , you may report to the DER that you have received an employee's laboratory confirmed positive, adulterated, or substituted test result, consistent with the terms of the waiver the employer received. You must not provide any further details about the test result (*e.g.,* the name of the drug involved).

(2) If the employer does not have a stand-down policy that meets the requirements of § 40.21 , you must not inform the employer that you have received an employee's laboratory confirmed positive, adulterated, or substituted test result until you verify the test result. For example, as an MRO employed directly by a company, you must not tell anyone on the company's staff or management that you have received an employee's laboratory confirmed test result.

§ 40.131 How does the MRO or DER notify an employee of the verification process after a confirmed positive, adulterated, substituted, or invalid test result?

(a) When, as the MRO, you receive a confirmed positive, adulterated, substituted, or invalid test result from the laboratory, you must contact the employee directly (*i.e.,* actually talk to the employee), on a confidential basis, to determine whether the employee wants to discuss the test result. In making this contact, you must explain to the employee that, if he or she declines to discuss the result, you will verify the test as positive or as a refusal to test because of adulteration or substitution, as applicable.

(b) As the MRO, staff under your personal supervision may conduct this initial contact for you.

(1) This staff contact must be limited to scheduling the discussion between you and the employee and explaining the consequences of the employee's declining to speak with you (*i.e.,* that the MRO will verify the test without input from the employee). If the employee declines to speak with you, the staff person must document the employee's decision, including the date and time.

(2) A staff person must not gather any medical information or information concerning possible explanations for the test result.

(3) A staff person may advise an employee to have medical information (*e.g.,* prescriptions, information forming the basis of a legitimate medical explanation for a confirmed positive test result) ready to present at the interview with the MRO.

(4) Since you are required to speak personally with the employee, face-to-face or on the phone, your staff must not inquire if the employee wishes to speak with you.

(c) As the MRO, you or your staff must make reasonable efforts to reach the employee at the day and evening telephone numbers listed on the CCF. Reasonable efforts include, as a minimum, three attempts, spaced reasonably over a 24-hour period, to reach the employee at the day and evening telephone numbers listed on the CCF. If you or your staff cannot reach the employee directly after making these efforts, you or your staff must take the following steps:

(1) Document the efforts you made to contact the employee, including dates and times. If both phone numbers are incorrect (*e.g.,* disconnected, wrong number), you may take the actions listed in paragraph (c)(2) of this section without waiting the full 24-hour period.

(2) Contact the DER, instructing the DER to contact the employee.

(i) You must simply direct the DER to inform the employee to contact you.

(ii) You must not inform the DER that the employee has a confirmed positive, adulterated, substituted, or invalid test result.

(iii) You must document the dates and times of your attempts to contact the DER, and you must document the name of the DER you contacted and the date and time of the contact.

(d) As the DER, you must attempt to contact the employee immediately, using procedures that protect, as much as possible, the confidentiality of the MRO's request that the employee contact the MRO. If you successfully contact the employee (*i.e.,* actually talk to the employee), you must document the date and time of the contact, and inform the MRO. You must inform the employee that he or she must contact the MRO within the next 72 hours and tell the employee the consequences of failing to do so (see § 40.133(a)(2)).

(1) As the DER, you must not inform anyone else working for the employer that you are seeking to contact the employee on behalf of the MRO.

(2) If, as the DER, you have made all reasonable efforts to contact the employee but failed to do so, you may place the employee on temporary medically unqualified status or medical leave. Reasonable efforts include, as a minimum, three attempts, spaced reasonably over a 24-hour period, to reach the employee at the day and evening telephone numbers listed on the CCF.

(i) As the DER, you must document the dates and times of these efforts.

(ii) If, as the DER, you are unable to contact the employee within this 24-hour period, you must leave a message for the employee by any practicable means (*e.g.,* voice mail, e-mail, letter) to contact the MRO and inform the MRO of the date and time of this attempted contact.

§ 40.133 Under what circumstances may the MRO verify a test as positive, or as a refusal to test because of adulteration or substitution, without interviewing the employee?

(a) As the MRO, you normally may verify a confirmed positive test (for any drug or drug metabolite, including opiates), or as a refusal to test because of adulteration or substitution, only after interviewing the employee as provided in §§ 40.135–40.145 . However, there are three circumstances in which you may verify such a result without an interview:

(1) You may verify a test result as a positive or refusal to test, as applicable, if the employee expressly declines the opportunity to discuss the test with you. You must maintain complete documentation of this occurrence, including notation of informing, or

attempting to inform, the employee of the consequences of not exercising the option to speak with the you.

(2) You may verify a test result as a positive or refusal to test, as applicable, if the DER has successfully made and documented a contact with the employee and instructed the employee to contact you and more than 72 hours have passed since the time the DER contacted the employee.

(3) You may verify a test result as a positive or refusal to test, as applicable, if neither you nor the DER, after making and documenting all reasonable efforts, has been able to contact the employee within ten days of the date on which the MRO receives the confirmed test result from the laboratory.

(b) As the MRO, when you verify a test result as a positive or refusal to test under this section, you must document the date, time and reason, following the instructions in § 40.163 .

(c) As the MRO, after you have verified a test result as a positive or refusal to test under this section and reported the result to the DER, you must allow the employee to present information to you within 60 days of the verification documenting that serious illness, injury, or other circumstances unavoidably precluded contact with the MRO and/or DER in the times provided. On the basis of such information, you may reopen the verification, allowing the employee to present information concerning whether there is a legitimate medical explanation for the confirmed test result.

§ 40.135 What does the MRO tell the employee at the beginning of the verification interview?

(a) As the MRO, you must tell the employee that the laboratory has determined that the employee's test result was positive, adulterated, substituted, or invalid, as applicable. You must also tell the employee of the drugs for which his or her specimen tested positive, or the basis for the finding of adulteration or substitution.

(b) You must explain the verification interview process to the employee and inform the employee that your decision will be based on information the employee provides in the interview.

(c) You must explain that, if further medical evaluation is needed for the verification process, the employee must comply with your request for this evaluation and that failure to do so is equivalent of expressly declining to discuss the test result.

(d) As the MRO, you must warn an employee who has a confirmed positive, adulterated, substituted or invalid test that you are required to provide to third parties drug test result information and medical information affecting the performance of safety-sensitive duties that the employee gives you in the verification process without the employee's consent (see § 40.327).

(1) You must give this warning to the employee before obtaining any medical information as part of the verification process.

(2) For purposes of this paragraph (d), medical information includes information on medications or other substances affecting the performance of safety-sensitive duties that the employee reports using or medical conditions the employee reports having.

(3) For purposes of this paragraph (d), the persons to whom this information may be provided include the employer, a SAP evaluating the employee as part of the return to duty process (see § 40.293(g)), DOT, another Federal safety agency (*e.g.*, the NTSB), or any state safety agency as required by state law.

(e) You must also advise the employee that, before informing any third party about any medication the employee is using pursuant to a legally valid prescription under the Controlled Substances Act, you will, if the employee consents, contact the prescribing physician to determine if the medication can be changed to one that does not make the employee medically unqualified or does not pose a significant safety risk.

§ 40.137 On what basis does the MRO verify test results involving marijuana, cocaine, amphetamines, or PCP?

(a) As the MRO, you must verify a confirmed positive test result for marijuana, cocaine, amphetamines, and/or PCP unless the employee presents a legitimate medical explanation for the presence of the drug(s)/metabolite(s) in his or her system.

(b) You must offer the employee an opportunity to present a legitimate medical explanation in all cases.

(c) The employee has the burden of proof that a legitimate medical explanation exists. The employee must present information meeting this burden at the time of the verification interview. As the MRO, you have discretion to extend the time available to the employee for this purpose for up to five days before verifying the test result, if you determine that there is a reasonable basis to believe that the employee will be able to produce relevant evidence concerning a legitimate medical explanation within that time.

(d) If you determine that there is a legitimate medical explanation, you must verify the test result as negative. Otherwise, you must verify the test result as positive.

(e) In determining whether a legitimate medical explanation exists, you may consider the employee's use of a medication from a foreign country. You must exercise your professional judgment consistently with the following principles:

(1) There can be a legitimate medical explanation only with respect to a substance that is obtained legally in a foreign country.

(2) There can be a legitimate medical explanation only with respect to a substance that has a legitimate medical use. Use of a drug of abuse (*e.g.*, heroin, PCP, marijuana) or any other substance (see § 40.151(f) and (g)) that cannot be viewed as having a legitimate medical use can never be the basis for a legitimate medical explanation, even if the substance is obtained legally in a foreign country.

(3) Use of the substance can form the basis of a legitimate medical explanation only if it is used consistently with its proper and intended medical purpose.

(4) Even if you find that there is a legitimate medical explanation under this paragraph (e) and verify a test negative, you may have a responsibility to raise fitness-for-duty considerations with the employer (see § 40.327).

§ 40.139 On what basis does the MRO verify test results involving opiates?

As the MRO, you must proceed as follows when you receive a laboratory confirmed positive opiate result:

(a) If the laboratory detects the presence of 6-acetylmorphine (6-AM) in the specimen, you must verify the test result positive.

(b) In the absence of 6-AM, if the laboratory detects the presence of either morphine or codeine at 15,000 ng/mL or above, you must verify the test result positive unless the employee presents a legitimate medical explanation for the presence of the drug or drug metabolite in his or her system, as in the case of other drugs (see § 40.137). Consumption of food products (*e.g.*, poppy seeds) must not be considered a legitimate medical explanation for the employee having morphine or codeine at these concentrations.

(c) For all other opiate positive results, you must verify a confirmed positive test result for opiates only if you determine that there is clinical evidence, in addition to the urine test, of unauthorized use of any opium, opiate, or opium derivative (i.e., morphine, heroin, or codeine).

(1) As an MRO, it is your responsibility to use your best

professional and ethical judgement and discretion to determine whether there is clinical evidence of unauthorized use of opiates. Examples of information that you may consider in making this judgement include, but are not limited to, the following:

(i) Recent needle tracks;

(ii) Behavioral and psychological signs of acute opiate intoxication or withdrawal;

(iii) Clinical history of unauthorized use recent enough to have produced the laboratory test result;

(iv) Use of a medication from a foreign country. See § 40.137(e) for guidance on how to make this determination.

(2) In order to establish the clinical evidence referenced in paragraphs (c)(1)(i) and (ii) of this section, personal observation of the employee is essential.

(i) Therefore, you, as the MRO, must conduct, or cause another physician to conduct, a face-to-face examination of the employee.

(ii) No face-to-face examination is needed in establishing the clinical evidence referenced in paragraph (c)(1)(iii) or (iv) of this section.

(3) To be the basis of a verified positive result for opiates, the clinical evidence you find must concern a drug that the laboratory found in the specimen. (For example, if the test confirmed the presence of codeine, and the employee admits to unauthorized use of hydrocodone, you do not have grounds for verifying the test positive. The admission must be for the substance that was found).

(4) As the MRO, you have the burden of establishing that there is clinical evidence of unauthorized use of opiates referenced in this paragraph (c). If you cannot make this determination (*e.g.*, there is not sufficient clinical evidence or history), you must verify the test as negative. The employee does not need to show you that a legitimate medical explanation exists if no clinical evidence is established.

§ 40.141 How does the MRO obtain information for the verification decision?

As the MRO, you must do the following as you make the determinations needed for a verification decision:

(a) You must conduct a medical interview. You must review the employee's medical history and any other relevant biomedical factors presented to you by the employee. You may direct the employee to undergo further medical evaluation by you or another physician.

(b) If the employee asserts that the presence of a drug or drug metabolite in his or her specimen results from taking prescription medication, you must review and take all reasonable and necessary steps to verify the authenticity of all medical records the employee provides. You may contact the employee's physician or other relevant medical personnel for further information.

§ 40.143 [Reserved]

§ 40.145 On what basis does the MRO verify test results involving adulteration or substitution?

(a) As an MRO, when you receive a laboratory report that a specimen is adulterated or substituted, you must treat that report in the same way you treat the laboratory's report of a confirmed positive test for a drug or drug metabolite.

(b) You must follow the same procedures used for verification of a confirmed positive test for a drug or drug metabolite (see §§ 40.129–40.135, 40.141, 40.151), except as otherwise provided in this section.

(c) In the verification interview, you must explain the laboratory findings to the employee and address technical questions or issues the employee may raise.

(d) You must offer the employee the opportunity to present a legitimate medical explanation for the laboratory findings with respect to presence of the adulterant in, or the creatinine and specific gravity findings for, the specimen.

(e) The employee has the burden of proof that there is a legitimate medical explanation.

(1) To meet this burden in the case of an adulterated specimen, the employee must demonstrate that the adulterant found by the laboratory entered the specimen through physiological means.

(2) To meet this burden in the case of a substituted specimen, the employee must demonstrate that he or she did produce or could have produced urine, through physiological means, meeting the creatinine and specific gravity criteria of § 40.93(b).

(3) The employee must present information meeting this burden at the time of the verification interview. As the MRO, you have discretion to extend the time available to the employee for this purpose for up to five days before verifying the specimen, if you determine that there is a reasonable basis to believe that the employee will be able to produce relevant evidence supporting a legitimate medical explanation within that time.

(f) As the MRO or the employer, you are not responsible for arranging, conducting, or paying for any studies, examinations or analyses to determine whether a legitimate medical explanation exists.

(g) As the MRO, you must exercise your best professional judgment in deciding whether the employee has established a legitimate medical explanation.

(1) If you determine that the employee's explanation does not present a reasonable basis for concluding that there may be a legitimate medical explanation, you must report the test to the DER as a verified refusal to test because of adulteration or substitution, as applicable.

(2) If you believe that the employee's explanation may present a reasonable basis for concluding that there is a legitimate medical explanation, you must direct the employee to obtain, within the five-day period set forth in paragraph (e)(3) of this section, a further medical evaluation. This evaluation must be performed by a licensed physician (the ''referral physician''), acceptable to you, with expertise in the medical issues raised by the employee's explanation. (The MRO may perform this evaluation if the MRO has appropriate expertise.)

(i) As the MRO or employer, you are not responsible for finding or paying a referral physician. However, on request of the employee, you must provide reasonable assistance to the employee's efforts to find such a physician. The final choice of the referral physician is the employee's, as long as the physician is acceptable to you.

(ii) As the MRO, you must consult with the referral physician, providing guidance to him or her concerning his or her responsibilities under this section. As part of this consultation, you must provide the following information to the referral physician:

(A) That the employee was required to take a DOT drug test, but the laboratory reported that the specimen was adulterated or substituted, which is treated as a refusal to test;

(B) The consequences of the appropriate DOT agency regulation for refusing to take the required drug test;

(C) That the referral physician must agree to follow the requirements of paragraphs (g)(3) through (g)(4) of this section; and

(D) That the referral physician must provide you with a signed statement of his or her recommendations.

(3) As the referral physician, you must evaluate the employee and consider any evidence the employee presents concerning the employee's medical explanation. You may conduct additional tests to determine whether

there is a legitimate medical explanation. Any additional urine tests must be performed in an HHS-certified laboratory.

(4) As the referral physician, you must then make a written recommendation to the MRO about whether the MRO should determine that there is a legitimate medical explanation. As the MRO, you must seriously consider and assess the referral physician's recommendation in deciding whether there is a legitimate medical explanation.

(5) As the MRO, if you determine that there is a legitimate medical explanation, you must cancel the test and inform ODAPC in writing of the determination and the basis for it (*e.g.*, referral physician's findings, evidence produced by the employee).

(6) As the MRO, if you determine that there is not a legitimate medical explanation, you must report the test to the DER as a verified refusal to test because of adulteration or substitution.

(h) The following are examples of types of evidence an employee could present to support an assertion of a legitimate medical explanation for a substituted result.

(1) Medically valid evidence demonstrating that the employee is capable of physiologically producing urine meeting the creatinine and specific gravity criteria of § 40.93(b) .

(i) To be regarded as medically valid, the evidence must have been gathered using appropriate methodology and controls to ensure its accuracy and reliability.

(ii) Assertion by the employee that his or her personal characteristics (*e.g.*, with respect to race, gender, weight, diet, working conditions) are responsible for the substituted result does not, in itself, constitute a legitimate medical explanation. To make a case that there is a legitimate medical explanation, the employee must present evidence showing that the cited personal characteristics actually result in the physiological production of urine meeting the creatinine and specific gravity criteria of § 40.93(b) .

(2) Information from a medical evaluation under paragraph (g) of this section that the individual has a medical condition that has been demonstrated to cause the employee to physiologically produce urine meeting the creatinine and specific gravity criteria of § 40.93(b) .

(i) A finding or diagnosis by the physician that an employee has a medical condition, in itself, does not constitute a legitimate medical explanation.

(ii) To establish there is a legitimate medical explanation, the employee must demonstrate that the cited medical condition actually results in the physiological production of urine meeting the creatinine and specific gravity criteria of § 40.93(b) .

§ 40.147 [Reserved]

§ 40.149 May the MRO change a verified positive drug test result or refusal to test?

(a) As the MRO, you may change a verified positive or refusal to test drug test result only in the following situations:

(1) When you have reopened a verification that was done without an interview with an employee (see § 40.133(c)).

(2) If you receive information, not available to you at the time of the original verification, demonstrating that the laboratory made an error in identifying (*e.g.,* a paperwork mistake) or testing (*e.g.,* a false positive or negative) the employee's primary or split specimen. For example, suppose the laboratory originally reported a positive test result for Employee X and a negative result for Employee Y. You verified the test results as reported to you. Then the laboratory notifies you that it mixed up the two test results, and X was really negative and Y was really positive. You would change X's test result from positive to negative and contact Y to conduct a verification interview.

(3) If, within 60 days of the original verification decision—

(i) You receive information that could not reasonably have been provided to you at the time of the decision demonstrating that there is a legitimate medical explanation for the presence of drug(s)/metabolite(s) in the employee's specimen; or

(ii) You receive credible new or additional evidence that a legitimate medical explanation for an adulterated or substituted result exists.

Example to Paragraph (a)(3): If the employee's physician provides you a valid prescription that he or she failed to find at the time of the original verification, you may change the test result from positive to negative if you conclude that the prescription provides a legitimate medical explanation for the drug(s)/ metabolite(s) in the employee's specimen.

(4) If you receive the information in paragraph (a)(3) of this section after the 60-day period, you must consult with ODAPC prior to changing the result.

(5) When you have made an administrative error and reported an incorrect result.

(b) If you change the result, you must immediately notify the DER in writing, as provided in §§ 40.163–40.165.

(c) You are the only person permitted to change a verified test result.

§ 40.151 What are MROs prohibited from doing as part of the verification process?

As an MRO, you are prohibited from doing the following as part of the verification process:

(a) You must not consider any evidence from tests of urine samples or other body fluids or tissues (*e.g.,* blood or hair samples) that are not collected or tested in accordance with this part. For example, if an employee tells you he went to his own physician, provided a urine specimen, sent it to a laboratory, and received a negative test result or a DNA test result questioning the identity of his DOT specimen, you are required to ignore this test result.

(b) In reviewing the CCF, you must not consider evidence extrinsic to the CCF in determining whether the test is valid. For example, you must review only what is on the face of the CCF for this purpose, not assertions by the employee that the CCF does not accurately reflect what happened at the collection site.

(c) It is not your function to determine whether the employer should have directed that a test occur. For example, if an employee tells you that the employer misidentified her as the subject of a random test, or directed her to take a reasonable suspicion or post-accident test without proper grounds under a DOT agency drug or alcohol regulation, you must inform the employee that you cannot play a role in deciding these issues.

(d) It is not your function to consider explanations of confirmed positive, adulterated, or substituted test results that would not, even if true, constitute a legitimate medical explanation. For example, an employee may tell you that someone slipped amphetamines into her drink at a party, that she unknowingly ingested a marijuana brownie, or that she traveled in a closed car with several people smoking crack. MROs are unlikely to be able to verify the facts of such passive or unknowing ingestion stories. Even if true, such stories do not present a legitimate medical explanation. Consequently, you must not declare a test as negative based on an explanation of this kind.

(e) You must not verify a test negative based on information that a physician recommended that the employee use a drug listed in Schedule I of the Controlled Substances Act. (*e.g.,* under a state law that purports to authorize such recommendations, such as the

''medical marijuana'' laws that some states have adopted).

(f) You must not accept an assertion of consumption or other use of a hemp or other non-prescription marijuana-related product as a basis for verifying a marijuana test negative. You also must not accept such an explanation related to consumption of coca teas as a basis for verifying a cocaine test result as negative. Consuming or using such a product is not a legitimate medical explanation.

(g) You must not accept an assertion that there is a legitimate medical explanation for the presence of PCP or 6-AM in a specimen. There are no legitimate medical explanations for the presence of these substances.

(h) You must not accept, as a legitimate medical explanation for an adulterated specimen, an assertion that soap, bleach, or glutaraldehyde entered a specimen through physiological means. There are no physiological means through which these substances can enter a specimen.

(i) You must not accept, as a legitimate medical explanation for a substituted specimen, an assertion that an employee can produce urine with no detectable creatinine. There are no physiological means through which a person can produce a urine specimen having this characteristic.

§ 40.153 How does the MRO notify employees of their right to a test of the split specimen?

(a) As the MRO, when you have verified a drug test as positive for a drug or drug metabolite, or as a refusal to test because of adulteration or substitution, you must notify the employee of his or her right to have the split specimen tested. You must also notify the employee of the procedures for requesting a test of the split specimen.

(b) You must inform the employee that he or she has 72 hours from the time you provide this notification to him or her to request a test of the split specimen.

(c) You must tell the employee how to contact you to make this request. You must provide telephone numbers or other information that will allow the employee to make this request. As the MRO, you must have the ability to receive the employee's calls at all times during the 72 hour period (*e.g.,* by use of an answering machine with a ''time stamp'' feature when there is no one in your office to answer the phone).

(d) You must tell the employee that if he or she makes this request within 72 hours, the employer must ensure that the test takes place, and that the employee is not required to pay for the test from his or her own funds before the test takes place. You must also tell the employee that the employer may seek reimbursement for the cost of the test (see § 40.173).

(e) You must tell the employee that additional tests of the specimen *e.g.,* DNA tests) are not authorized.

§ 40.155 What does the MRO do when a negative or positive test result is also dilute?

(a) When the laboratory reports that a specimen is dilute, you must, as the MRO, report to the DER that the specimen, in addition to being negative or positive, is dilute.

(b) You must check the ''dilute'' box (Step 6) on Copy 2 of the CCF.

(c) You may only report a dilute test result when you are in possession of a legible copy of Copy 1 of the CCF. In addition, you must have Copy 2 of the CCF, a legible copy of it, or any other copy of the CCF containing the employee's signature.

(d) When you report a dilute specimen to the DER, you must explain to the DER the employer's obligations and choices under § 40.197.

§ 40.157 [Reserved]

§ 40.159 What does the MRO do when a drug test result is invalid?

(a) As the MRO, when the laboratory reports that the test result is an invalid result, you must do the following:

(1) Discuss the laboratory results with a certifying scientist to obtain more specific information.

(2) Contact the employee and inform the employee that the specimen was invalid or contained an unexplained interfering substance. In contacting the employee, use the procedures set forth in § 40.131.

(3) After explaining the limits of disclosure (see §§ 40.135(d) and 40.327), you should inquire as to medications the employee may have taken that may interfere with some immunoassay tests.

(4) If the employee gives an explanation that is acceptable, you must:

(i) Place a check mark in the ''Test Cancelled'' box (Step 6) on Copy 2 of the CCF and enter ''Invalid Result'' and ''direct observation collection not required'' on the ''Remarks'' line.

(ii) Report to the DER that the test is cancelled, the reason for cancellation, and that no further action is required unless a negative test result is required (*i.e.,* pre-employment, return-to-duty, or follow-up tests).

(5) If the employee is unable to provide an explanation and/or a valid prescription for a medication that interfered with the immunoassay test but denies having adulterated the specimen, you must:

(i) Place a check mark in the ''Test Cancelled'' box (Step 6) on Copy 2 of the CCF and enter ''Invalid Result'' and ''direct observation collection required'' on the ''Remarks'' line.

(ii) Report to the DER that the test is cancelled, the reason for cancellation, and that a second collection must take place immediately under direct observation.

(iii) Instruct the employer to ensure that the employee has the minimum possible advance notice that he or she must go to the collection site.

(b) You may only report an invalid test result when you are in possession of a legible copy of Copy 1 of the CCF. In addition, you must have Copy 2 of the CCF, a legible copy of it, or any other copy of the CCF containing the employee's signature.

(c) If the employee admits to having adulterated or substituted the specimen, you must, on the same day, write and sign your own statement of what the employee told you. You must then report a refusal to test in accordance with § 40.163 .

§ 40.161 What does the MRO do when a drug test specimen is rejected for testing?

As the MRO, when the laboratory reports that the specimen is rejected for testing (*e.g.,* because of a fatal or uncorrected flaw), you must do the following:

(a) Place a check mark in the ''Test Cancelled'' box (Step 6) on Copy 2 of the CCF and enter the reason on the ''Remarks'' line.

(b) Report to the DER that the test is cancelled and the reason for cancellation, and that no further action is required unless a negative test is required (*e.g.,* in the case of a pre-employment, return-to-duty, or follow-up test).

(c) You may only report a test cancelled because of a rejected for testing test result when you are in possession of a legible copy of Copy 1 of the CCF. In addition, you must have Copy 2 of the CCF, a legible copy of it, or any other copy of the CCF containing the employee's signature.

§ 40.163 How does the MRO report drug test results?

(a) As the MRO, it is your responsibility to report the drug test results to the employer in writing.

(1) You or a staff member may rubber stamp a report of negative results. If you use a rubber stamp, you or your staff must also initial the stamp to identify who affixed the stamp to the report.

(2) You, as the MRO, must sign reports of all other results.

(b) You may use a signed or stamped and dated legible photocopy of Copy 2 of the CCF to report test results.

(c) If you do not report test results using Copy 2 of the CCF for this purpose, you must provide a written report (*e.g.,* a letter) for each test result. This report must, as a minimum, include the following information:

(1) Full name, as indicated on the CCF, of the employee tested;

(2) Specimen ID number from the CCF and the donor SSN or employee ID number;

(3) Reason for the test as indicated on the CCF (*e.g.,* random, post-accident);

(4) Date of the collection;

(5) Result of the test (*i.e.,* positive, negative, dilute, refusal to test, test cancelled) and the date the result was verified by the MRO;

(6) For verified positive tests, the drug(s)/metabolite(s) for which the test was positive;

(7) For cancelled tests, the reason for cancellation; and

(8) For refusals to test, the reason for the refusal determination (e.g., in the case of an adulterated test result, the name of the adulterant).

(d) You must retain a signed or stamped and dated copy of Copy 2 of the CCF in your records. If you do not use Copy 2 for reporting results, you must maintain a copy of the signed or stamped and dated letter in addition to the signed or stamped and dated Copy 2.

(e) You must not use Copy 1 of the CCF to report drug test results.

(f) You must not provide quantitative values to the DER or C/TPA for drug or validity test results. However, you must provide the test information in your possession to a SAP who consults with you (see § 40.293(g)).

§ 40.165 To whom does the MRO transmit reports of drug test results?

(a) As the MRO, you must report all drug test results to the DER, except in the circumstances provided for in § 40.345 .

(b) If the employer elects to receive reports of results through a C/TPA, acting as an intermediary as provided in § 40.345 , you must report the results through the designated C/TPA.

§ 40.167 How are MRO reports of drug results transmitted to the employer?

As the MRO or C/TPA who transmits drug test results to the employer, you must comply with the following requirements:

(a) You must report the results in a confidential manner.

(b) You must transmit to the DER on the same day the MRO verifies the result or the next business day all verified positive test results, results requiring an immediate collection under direct observation, adulterated or substituted specimen results, and other refusals to test.

(1) Direct telephone contact with the DER is the preferred method of immediate reporting. Follow up your phone call with appropriate documentation (see § 40.163).

(2) You are responsible for identifying yourself to the DER, and the DER must have a means to confirm your identification.

(3) The MRO's report that you transmit to the employer must contain all of the information required by § 40.163 .

(c) You must transmit the MRO's written report of verified test to the DER so that the DER receives them within two days of verification by the MRO.

(d) In transmitting test results, you or the C/TPA and the employer must ensure the security of the transmission and limit access to any transmission, storage, or retrieval systems.

§ 40.169 Where is other information concerning the role of MROs and the verification process found in this regulation?

You can find more information concerning the role of MROs in several sections of this part:

§ 40.3—Definition.
§ § 40.47–40.49—Correction of form and kit errors.
§ 40.67—Role in direct observation and other atypical test situations.
§ 40.83—Laboratory handling of fatal and correctable flaws.
§ 40.97—Laboratory handling of test results and quantitative values.
§ 40.99—Authorization of longer laboratory retention of specimens.
§ 40.101—Relationship with laboratories; avoidance of conflicts of interest.
§ 40.105—Notification of discrepancies in blind specimen results.
§ 40.171—Request for test of split specimen.
§ 40.187—Action concerning split specimen test results.
§ 40.193—Role in ''shy bladder'' situations.
§ 40.195—Role in cancelling tests.
§§ 40.199–40.203—Documenting errors in tests.
§ 40.327—Confidentiality and release of information.
§ 40.347—Transfer of records.
§ 40.353—Relationships with service agents.

Subpart H—Split Specimen Tests

§ 40.171 How does an employee request a test of a split specimen?

(a) As an employee, when the MRO has notified you that you have a verified positive drug test or refusal to test because of adulteration or substitution, you have 72 hours from the time of notification to request a test of the split specimen. The request may be verbal or in writing. If you make this request to the MRO within 72 hours, you trigger the requirements of this section for a test of the split specimen.

(b)(1) If, as an employee, you have not requested a test of the split specimen within 72 hours, you may present to the MRO information documenting that serious injury, illness, lack of actual notice of the verified test result, inability to contact the MRO (*e.g.*, there was no one in the MRO's office and the answering machine was not working), or other circumstances unavoidably prevented you from making a timely request.

(2) As the MRO, if you conclude from the employee's information that there was a legitimate reason for the employee's failure to contact you within 72 hours, you must direct that the test of the split specimen take place, just as you would when there is a timely request.

(c) When the employee makes a timely request for a test of the split specimen under paragraphs (a) and (b) of this section, you must, as the MRO, immediately provide written notice to the laboratory that tested the primary specimen, directing the laboratory to forward the split specimen to a second HHS-certified laboratory. You must also document the date and time of the employee's request.

§ 40.173 Who is responsible for paying for the test of a split specimen?

(a) As the employer, you are responsible for making sure (*e.g.*, by establishing appropriate accounts with laboratories for testing split specimens) that the MRO, first laboratory, and second laboratory perform the functions noted in §§ 40.175–40.185 in a timely manner, once the employee has made a timely request for a test of the split specimen.

(b) As the employer, you must not condition your compliance with these requirements on the employee's direct payment to the MRO or laboratory or the employee's agreement to reimburse you for the costs of testing. For example, if you ask the employee to pay for some or all of the cost of testing the split specimen, and the employee is unwilling or unable to do so, you must ensure that the test takes place in a timely manner, even though this means that you pay for it.

(c) As the employer, you may seek payment or reimbursement of all or part of the cost of the split specimen from the employee (*e.g.*, through your written company policy or a collective bargaining agreement). This part takes

no position on who ultimately pays the cost of the test, so long as the employer ensures that the testing is conducted as required and the results released appropriately.

§ 40.175 What steps does the first laboratory take with a split specimen?

(a) As the laboratory at which the primary and split specimen first arrive, you must check to see whether the split specimen is available for testing.

(b) If the split specimen is unavailable or appears insufficient, you must then do the following:

(1) Continue the testing process for the primary specimen as you would normally. Report the results for the primary specimen without providing the MRO information regarding the unavailable split specimen.

(2) Upon receiving a letter from the MRO instructing you to forward the split specimen to another laboratory for testing, report to the MRO that the split specimen is unavailable for testing. Provide as much information as you can about the cause of the unavailability.

(c) As the laboratory that tested the primary specimen, you are not authorized to open the split specimen under any circumstances (except when the split specimen is redesignated as provided in § 40.83).

(d) When you receive written notice from the MRO instructing you to send the split specimen to another HHS-certified laboratory, you must forward the following items to the second laboratory:

(1) The split specimen in its original specimen bottle, with the seal intact;

(2) A copy of the MRO's written request; and

(3) A copy of Copy 1 of the CCF, which identifies the drug(s)/metabolite(s) or the validity criteria to be tested for.

(e) You must not send to the second laboratory any information about the identity of the employee. Inadvertent disclosure does not, however, cause a fatal flaw.

(f) This subpart does not prescribe who gets to decide which HHS-certified laboratory is used to test the split specimen. That decision is left to the parties involved.

§ 40.177 What does the second laboratory do with the split specimen when it is tested to reconfirm the presence of a drug or drug metabolite?

(a) As the laboratory testing the split specimen, you must test the split specimen for the drug(s)/drug metabolite(s) detected in the primary specimen.

(b) You must conduct this test without regard to the cutoff concentrations of § 40.87 .

(c) If the test fails to reconfirm the presence of the drug(s)/drug metabolite(s) that were reported positive in the primary specimen, you must conduct validity tests in an attempt to determine the reason for being unable to reconfirm the presence of the drug(s)/metabolite(s). You should conduct the same validity tests as you would conduct on a primary specimen set forth in § 40.91 .

(d) In addition, if the test fails to reconfirm the presence of the drugs/drugs metabolites or validity criteria that were reported in the primary specimen, you may transmit the specimen or an aliquot of it to another HHS-certified laboratory that will conduct another reconfirmation test.

§ 40.179 What does the second laboratory do with the split specimen when it is tested to reconfirm an adulterated test result?

As the laboratory testing the split specimen, you must test the split specimen for the adulterant detected in the primary specimen, using the criteria of § 40.95 just as you would do for a primary specimen. The result of the primary specimen is reconfirmed if the split specimen meets these criteria.

§ 40.181 What does the second laboratory do with the split specimen when it is tested to reconfirm a substituted test result?

As the laboratory testing the split specimen, you must test the split specimen using the criteria of § 40.93(b), just as you would do for a primary specimen. The result of the primary specimen is reconfirmed if the split specimen meets these criteria.

§ 40.183 What information do laboratories report to MROs regarding split specimen results?

(a) As the laboratory responsible for testing the split specimen, you must report split specimen test results by checking the ''Reconfirmed'' box or the ''Failed to Reconfirm'' box (Step 5(b)) on Copy 1 of the CCF.

(b) If you check the ''Failed to Reconfirm'' box, one of the following statements must be included (as appropriate) on the ''Reason'' line (Step 5(b)):

(1) ''Drug(s)/Drug Metabolite(s) Not Detected.''

(2) ''Adulterant not found within criteria.''

(3) ''Specimen not consistent with substitution criteria [specify creatinine, specific gravity, or both]''

(4) ''Specimen not available for testing.''

(c) As the laboratory certifying scientist, enter your name, sign, and date the CCF.

§ 40.185 Through what methods and to whom must a laboratory report split specimen results?

(a) As the laboratory testing the split specimen, you must report laboratory results directly, and only, to the MRO at his or her place of business. You must not report results to or through the DER or another service agent (*e.g.*, a C/TPA).

(b) You must fax, courier, mail, or electronically transmit a legible image or copy of the fully-completed Copy 1 of the CCF, which has been signed by the certifying scientist.

(c) You must transmit the laboratory result to the MRO immediately, preferably on the same day or next business day as the result is signed and released.

§ 40.187 What does the MRO do with split specimen laboratory results?

As an MRO, you must take the following actions when a laboratory reports the following results of split specimen tests:

(a) *Reconfirmed.* (1) In the case of a reconfirmed positive test for a drug or drug metabolite, report the reconfirmation to the DER and the employee.

(2) In the case of a reconfirmed adulterated or substituted result, report to the DER and the employee that the specimen was adulterated or substituted, either of which constitutes a refusal to test. Therefore, ''refusal to test'' is the final result.

(b) *Failed to Reconfirm: Drug(s)/Drug Metabolite(s) Not Detected.* (1) Report to the DER and the employee that both tests must be cancelled.

(2) Using the format in Appendix D to this part, inform ODAPC of the failure to reconfirm.

(c) *Failed to Reconfirm: Adulteration or Substitution (as appropriate) Criteria Not Met.* (1) Report to the DER and the employee that both tests must be cancelled.

(2) Using the format in Appendix D to this part, inform ODAPC of the failure to reconfirm.

(d) *Failed to Reconfirm: Specimen not Available for Testing.* (1) Report to the DER and the employee that both tests must be cancelled and the reason for cancellation.

(2) Direct the DER to ensure the immediate collection of another specimen from the employee under direct observation, with no notice given to the employee of this collection requirement until immediately before the collection.

(3) Using the format in Appendix D to this part, notify ODAPC of the failure to reconfirm.

(e) Enter your name, sign and date (Step 7) of Copy 2 of the CCF.

(f) Send a legible copy of Copy 2 of the CCF (or a signed and dated letter, see § 40.163) to the employer and keep a copy for your records. Transmit the document as provided in § 40.167.

§ 40.189 Where is other information concerning split specimens found in this regulation?

You can find more information concerning split specimens in several sections of this part:

§ 40.3—Definition.
§ 40.65—Quantity of split specimen.
§ 40.67—Directly observed test when split specimen is unavailable.
§§ 40.71–40.73—Collection process for split specimens.
§ 40.83—Laboratory accessioning of split specimens.
§ 40.99—Laboratory retention of split specimens.
§ 40.103—Blind split specimens.
§ 40.153—MRO notice to employees on tests of split specimen.
§§ 40.193 and 40.201—MRO actions on insufficient or unavailable split specimens.
Appendix D to Part 40—Report format for split specimen failure to reconfirm.

Subpart I—Problems in Drug Tests

§ 40.191 What is a refusal to take a DOT drug test, and what are the consequences?

(a) As an employee, you have refused to take a drug test if you:

(1) Fail to appear for any test within a reasonable time, as determined by the employer, after being directed to do so by the employer. This includes the failure of an employee (including an owner-operator) to appear for a test when called by C/TPA (see § 40.61(a));

(2) Fail to remain at the testing site until the testing process is complete;

(3) Fail to provide a urine specimen for any drug test required by this part or DOT agency regulations;

(4) In the case of a directly observed or monitored collection in a drug test, fail to permit the observation or monitoring of your provision of a specimen (see §§ 40.67(l) and 40.69(g));

(5) Fail to provide a sufficient amount of urine when directed, and it has been determined, through a required medical evaluation, that there was no adequate medical explanation for the failure (see § 40.193(d)(2));

(6) Fail or decline to take a second test the employer or collector has directed you to take;

(7) Fail to undergo a medical examination or evaluation, as directed by the MRO as part of the verification process, or as directed by the DER as part of the ''shy bladder'' procedures of this part (see § 40.193(d)); or

(8) Fail to cooperate with any part of the testing process (*e.g.*, refuse to empty pockets when so directed by the collector, behave in a confrontational way that disrupts the collection process).

(b) As an employee, if the MRO reports that you have a verified adulterated or substituted test result, you have refused to take a drug test.

(c) As an employee, if you refuse to take a drug test, you incur the consequences specified under DOT agency regulations for a violation of those DOT agency regulations.

(d) As a collector or an MRO, when an employee refuses to participate in the part of the testing process in which you are involved, you must terminate the portion of the testing process in which you are involved, document the refusal on the CCF (or in a separate document which you cause to be attached to the form), immediately notify the DER by any means (*e.g.*, telephone or secure fax machine) that ensures that the refusal notification is immediately received. As a referral physician (*e.g.*, physician evaluating a ''shy bladder'' condition or a claim of a legitimate medical explanation in a validity testing situation), you must notify the MRO, who in turn will notify the DER.

(1) As the collector, you must note the refusal in the ''Remarks'' line (Step 2), and sign and date the CCF.

(2) As the MRO, you must note the refusal by checking the ''refused to test because'' box (Step 6) on Copy 2 of the CCF, and add the reason on the ''Remarks'' line. You must then sign and date the CCF.

(e) As an employee, when you refuse to take a non-DOT test or to sign a non-DOT form, you have not refused to take a DOT test. There are no consequences under DOT agency regulations for refusing to take a non-DOT test.

§ 40.193 What happens when an employee does not provide a sufficient amount of urine for a drug test?

(a) This section prescribes procedures for situations in which an employee does not provide a sufficient amount of urine to permit a drug test (*i.e.,* 45 mL of urine).

(b) As the collector, you must do the following:

(1) Discard the insufficient specimen, except where the insufficient specimen was out of temperature range or showed evidence of adulteration or tampering (see § 40.65(b) and (c)).

(2) Urge the employee to drink up to 40 ounces of fluid, distributed reasonably through a period of up to three hours, or until the individual has provided a sufficient urine specimen, whichever occurs first. It is not a refusal to test if the employee declines to drink.

(3) If the employee refuses to make the attempt to provide a new urine specimen, you must discontinue the collection, note the fact on the ''Remarks'' line of the CCF (Step 2), and immediately notify the DER. This is a refusal to test.

(4) If the employee has not provided a sufficient specimen within three hours of the first unsuccessful attempt to provide the specimen, you must discontinue the collection, note the fact on the ''Remarks'' line of the CCF (Step 2), and immediately notify the DER.

(5) Send Copy 2 of the CCF to the MRO and Copy 4 to the DER. You must send or fax these copies to the MRO and DER within 24 hours or the next business day.

(c) As the DER, when the collector informs you that the employee has not provided a sufficient amount of urine (see paragraph (b)(4) of this section), you must, after consulting with the MRO, direct the employee to obtain, within five working days, an evaluation from a licensed physician, acceptable to the MRO, who has expertise in the medical issues raised by the employee's failure to provide a sufficient specimen. (The MRO may perform this evaluation if the MRO has appropriate expertise.)

(1) As the MRO, if another physician will perform the evaluation, you must provide the other physician with the following information and instructions:

(i) That the employee was required to take a DOT drug test, but was unable to provide a sufficient amount of urine to complete the test;

(ii) The consequences of the appropriate DOT agency regulation for refusing to take the required drug test;

(iii) That the referral physician must agree to follow the requirements of paragraphs (d) through (g) of this section.

(d) As the referral physician conducting this evaluation, you must recommend that the MRO make one of the following determinations:

(1) A medical condition has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of urine. As the MRO, if you accept this recommendation, you must:

(i) Check ''Test Cancelled'' (Step 6) on the CCF; and

(ii) Sign and date the CCF.

(2) There is not an adequate basis for determining that a medical condition has, or with a high degree of probability could have, precluded the employee

from providing a sufficient amount of urine. As the MRO, if you accept this recommendation, you must:

(i) Check ''Refusal to test because'' (Step 6) on the CCF and enter reason in the remarks line; and

(ii) Sign and date the CCF.

(e) For purposes of this paragraph, a medical condition includes an ascertainable physiological condition (*e.g.,* a urinary system dysfunction) or a medically documented pre-existing psychological disorder, but does not include unsupported assertions of ''situational anxiety'' or dehydration.

(f) As the referral physician making the evaluation, after completing your evaluation, you must provide a written statement of your recommendations and the basis for them to the MRO. You must not include in this statement detailed information on the employee's medical condition beyond what is necessary to explain your conclusion.

(g) If, as the referral physician making this evaluation in the case of a pre-employment test, you determine that the employee's medical condition is a serious and permanent or long-term disability that is highly likely to prevent the employee from providing a sufficient amount of urine for a very long or indefinite period of time, you must set forth your determination and the reasons for it in your written statement to the MRO. As the MRO, upon receiving such a report, you must follow the requirements of § 40.195, where applicable.

(h) As the MRO, you must seriously consider and assess the referral physician's recommendations in making your determination about whether the employee has a medical condition that has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of urine. You must report your determination to the DER in writing as soon as you make it.

(i) As the employer, when you receive a report from the MRO indicating that a test is cancelled as provided in paragraph (d)(1) of this section, you take no further action with respect to the employee. The employee remains in the random testing pool.

§ 40.195 What happens when an individual is unable to provide a sufficient amount of urine for a pre-employment or return-to-duty test because of a permanent or long-term medical condition?

(a) This section concerns a situation in which an employee has a medical condition that precludes him or her from providing a sufficient specimen for a pre-employment or return-to-duty test and the condition involves a permanent or long-term disability. As the MRO in this situation, you must do the following:

(1) You must determine if there is clinical evidence that the individual is an illicit drug user. You must make this determination by personally conducting, or causing to be conducted, a medical evaluation and through consultation with the employee's physician and/or the physician who conducted the evaluation under § 40.193(d).

(2) If you do not personally conduct the medical evaluation, you must ensure that one is conducted by a licensed physician acceptable to you.

(3) For purposes of this section, the MRO or the physician conducting the evaluation may conduct an alternative test (*e.g.,* blood) as part of the medically appropriate procedures in determining clinical evidence of drug use.

(b) If the medical evaluation reveals no clinical evidence of drug use, as the MRO, you must report the result to the employer as a negative test with written notations regarding results of both the evaluation conducted under § 40.193(d) and any further medical examination. This report must state the basis for the determination that a permanent or long-term medical condition exists, making provision of a sufficient urine specimen impossible, and for the determination that no signs and symptoms of drug use exist.

(1) Check ''Negative'' (Step 6) on the CCF.

(2) Sign and date the CCF.

(c) If the medical evaluation reveals clinical evidence of drug use, as the MRO, you must report the result to the employer as a cancelled test with written notations regarding results of both the evaluation conducted under § 40.193(d) and any further medical examination. This report must state that a permanent or long-term medical condition exists, making provision of a sufficient urine specimen impossible, and state the reason for the determination that signs and symptoms of drug use exist. Because this is a cancelled test, it does not serve the purposes of a negative test (*i.e.,* the employer is not authorized to allow the employee to begin or resume performing safety-sensitive functions, because a negative test is needed for that purpose).

(d) For purposes of this section, permanent or long-term medical conditions are those physiological, anatomic, or psychological abnormalities documented as being present prior to the attempted collection, and considered not amenable to correction or cure for an extended period of time, if ever.

(1) Examples would include destruction (any cause) of the glomerular filtration system leading to renal failure; unrepaired traumatic disruption of the urinary tract; or a severe psychiatric disorder focused on genito-urinary matters.

(2) Acute or temporary medical conditions, such as cystitis, urethritis or prostatitis, though they might interfere with collection for a limited period of time, cannot receive the same exceptional consideration as the permanent or long-term conditions discussed in paragraph (d)(1) of this section.

§ 40.197 What happens when an employer receives a report of a dilute specimen?

(a) As the employer, if the MRO informs you that a positive drug test was dilute, you simply treat the test as a verified positive test. You must not direct the employee to take another test based on the fact that the specimen was dilute.

(b) If the MRO informs you that a negative drug test was dilute, you may, but are not required to, direct the employee to take another test immediately. Such recollections must not be collected under direct observation, unless there is another basis for use of direct observation (see § 40.67(b) and (c)).

(c) You must treat all employees the same for this purpose. For example, you must not retest some employees and not others. You may, however, establish different policies for different types of tests (*e.g.,* conduct retests in pre-employment test situations, but not in random test situations). You must inform your employees in advance of your decisions on these matters.

(d) If you direct the employee to take another test, you must ensure that the employee is given the minimum possible advance notice that he or she must go to the collection site.

(e) If you direct the employee to take another test, the result of the second test—not that of the original test—becomes the test of record, on which you rely for purposes of this part.

(f) If you require employees to take another test, and the second test is also negative and dilute, you are not permitted to make the employee take a third test because the second test was dilute.

(g) If you direct the employee to take another test and the employee declines to do so, the employee has refused the test for purpose of this part and DOT agency regulations.

§ 40.199 What problems always cause a drug test to be cancelled?

(a) As the MRO, when the laboratory discovers a ''fatal flaw'' during its processing of incoming specimens (see § 40.83), the laboratory will report to you that the specimen has been ''Rejected for Testing'' (with the reason stated). You must always cancel such a test.

(b) The following are ''fatal flaws'':

(1) There is no printed collector's name *and* no collector's signature;

(2) The specimen ID numbers on the specimen bottle and the CCF do not match;

(3) The specimen bottle seal is broken or shows evidence of tampering (and a split specimen cannot be redesignated, see § 40.83(g)); and

(4) Because of leakage or other causes, there is an insufficient amount of urine in the primary specimen bottle for analysis and the specimens cannot be redesignated (see § 40.83(g)).

(c) You must report the result as provided in § 40.161 .

§ 40.201 What problems always cause a drug test to be cancelled and may result in a requirement for another collection?

As the MRO, you must cancel a drug test when a laboratory reports that any of the following problems have occurred. You must inform the DER that the test was cancelled. You must also direct the DER to ensure that an additional collection occurs immediately, if required by the applicable procedures specified in paragraphs (a) through (e) of this section.

(a) The laboratory reports an ''Invalid Result.'' You must follow applicable procedures in § 40.159 (recollection under direct observation may be required).

(b) The laboratory reports the result as ''Rejected for Testing.'' You must follow applicable procedures in § 40.161 (a recollection may be required).

(c) The laboratory's test of the primary specimen is positive and the split specimen is reported by the laboratory as ''Failure to Reconfirm: Drug(s)/Drug Metabolite(s) Not Detected.'' You must follow applicable procedures in § 40.187(b) (no recollection is required in this case).

(d) The laboratory's test result for the primary specimen is adulterated or substituted and the split specimen is reported by the laboratory as ''Adulterant not found within criteria,'' or '' specimen not consistent with substitution criteria, as applicable. You must follow applicable procedures in § 40.187(c) (no recollection is required in this case).

(e) The laboratory's test of the primary specimen is positive, adulterated, or substituted and the split specimen is unavailable for testing. You must follow applicable procedures in § 40.187(d) (recollection under direct observation is required in this case).

(f) The examining physician has determined that there is an acceptable medical explanation of the employee's failure to provide a sufficient amount of urine. You must follow applicable procedures in § 40.193(d)(1) (no recollection is required in this case).

§ 40.203 What problems cause a drug test to be cancelled unless they are corrected?

(a) As the MRO, when a laboratory discovers a ''correctable flaw'' during its processing of incoming specimens (see § 40.83), the laboratory will attempt to correct it. If the laboratory is unsuccessful in this attempt, it will report to you that the specimen has been ''Rejected for Testing'' (with the reason stated).

(b) The following are ''correctable flaws'' that laboratories must attempt to correct:

(1) The collector's signature is omitted on the certification statement on the CCF.

(2) The specimen temperature was not checked and the ''Remarks'' line did not contain an entry regarding the temperature being out of range.

(c) As the MRO, when you discover a ''correctable flaw'' during your review of the CCF, you must cancel the test unless the flaw is corrected.

(d) The following are correctable flaws that you must attempt to correct:

(1) The employee's signature is omitted from the certification statement, unless the employee's failure or refusal to sign is noted on the ''Remarks'' line of the CCF.

(2) The certifying scientist's signature is omitted on the laboratory copy of the CCF for a positive, adulterated, substituted, or invalid test result.

(3) The collector uses a non-DOT form for the test, provided that the collection and testing process is conducted in accordance with DOT procedures in an HHS-certified laboratory following DOT initial and confirmation test criteria.

§ 40.205 How are drug test problems corrected?

(a) As a collector, you have the responsibility of trying to successfully complete a collection procedure for each employee.

(1) If, during or shortly after the collection process, you become aware of any event that prevents the completion of a valid test or collection (*e.g.,* a procedural or paperwork error), you must try to correct the problem promptly, if doing so is practicable. You may conduct another collection as part of this effort.

(2) If another collection is necessary, you must begin the new collection procedure as soon as possible, using a new CCF and a new collection kit.

(b) If, as a collector, laboratory, MRO, employer, or other person implementing these drug testing regulations, you become aware of a problem that can be corrected (see § 40.203), but which has not already been corrected under paragraph (a) of this section, you must take all practicable action to correct the problem so that the test is not cancelled.

(1) If the problem resulted from the omission of required information, you must, as the person responsible for providing that information, supply in writing the missing information and a statement that it is true and accurate. For example, suppose you are a collector, and you forgot to make a notation on the ''Remarks'' line of the CCF that the employee did not sign the certification. You would, when the problem is called to your attention, supply a signed statement that the employee failed or refused to sign the certification and that your statement is true and accurate. You must supply this information on the same business day on which you are notified of the problem, transmitting it by fax or courier.

(2) If the problem is the use of a non-Federal form, you must, as the person responsible for the use of the incorrect form, provide a signed statement that the incorrect form contains all the information needed for a valid DOT drug test, that the incorrect form was used inadvertently or as the only means of conducting a test, in circumstances beyond your control. The statement must also list the steps you have taken to prevent future use of non-Federal forms for DOT tests. For this flaw to have been corrected, the test of the specimen must have occurred at a HHS-certified laboratory where it was tested using the testing protocol in this part. You must supply this information on the same business day on which you are notified of the problem, transmitting it by fax or courier.

(3) You must maintain the written documentation of a correction with the CCF.

(4) You must mark the CCF in such a way (*e.g.,* stamp noting correction) as to make it obvious on the face of the CCF that you corrected the flaw.

(c) If the correction does not take place, as the MRO you must cancel the test.

§ 40.207 What is the effect of a cancelled drug test?

(a) A cancelled drug test is neither positive nor negative.

(1) As an employer, you must not attach to a cancelled test the consequences of a positive test or other violation of a DOT drug testing regulation (*e.g.,* removal from a safety-sensitive position).

(2) As an employer, you must not use a cancelled test for the purposes of a negative test to authorize the employee to perform safety-sensitive functions (*i.e.,* in the case of a pre-employment, return-to-duty, or follow-up test).

(3) However, as an employer, you must not direct a recollection for an employee because a test has been cancelled, except in the situations cited in paragraph (a)(2) of this section or other provisions of this part that require another test to be conducted (*e.g.,* §§ 40.159(a)(5) and 40.187(b)).

(b) A cancelled test does not count toward compliance with DOT requirements (*e.g.,* being applied toward the number of tests needed to meet the employer's minimum random testing rate).

(c) A cancelled DOT test does not provide a valid basis for an employer to conduct a non-DOT test (*i.e.,* a test under company authority).

§ 40.209 What is the effect of procedural problems that are not sufficient to cancel a drug test?

(a) As a collector, laboratory, MRO, employer or other person administering the drug testing process, you must document any errors in the testing process of which you become aware, even if they are not considered problems that will cause a test to be cancelled as listed in this subpart. Decisions about the ultimate impact of these errors will be determined by other administrative or legal proceedings, subject to the limitations of paragraph (b) of this section.

(b) No person concerned with the testing process may declare a test cancelled based on an error that does not have a significant adverse effect on the right of the employee to have a fair and accurate test. Matters that do not result in the cancellation of a test include, but are not limited to, the following:

(1) A minor administrative mistake (*e.g.,* the omission of the employee's middle initial, a transposition of numbers in the employee's social security number);

(2) An error that does not affect employee protections under this part (*e.g.,* the collector's failure to add bluing agent to the toilet bowl, which adversely affects only the ability of the collector to detect tampering with the specimen by the employee);

(3) The collection of a specimen by a collector who is required to have been trained (see § 40.33), but who has not met this requirement;

(4) A delay in the collection process (see § 40.61(a));

(5) Verification of a test result by an MRO who has the basic credentials to be qualified as an MRO (see § 40.121(a) through (b)) but who has not met training and/or documentation requirements (see § 40.121(c) through (e));

(6) The failure to directly observe or monitor a collection that the rule requires or permits to be directly observed or monitored, or the unauthorized use of direct observation or monitoring for a collection;

(7) The fact that a test was conducted in a facility that does not meet the requirements of § 40.41;

(8) If the specific name of the courier on the CCF is omitted or erroneous;

(9) Personal identifying information is inadvertently contained on the CCF (*e.g.,* the employee signs his or her name on the laboratory copy); or

(10) Claims that the employee was improperly selected for testing.

(c) As an employer, these types of errors, even though not sufficient to cancel a drug test result, may subject you to enforcement action under DOT agency regulations.

Subpart J—Alcohol Testing Personnel

§ 40.211 Who conducts DOT alcohol tests?

(a) Screening test technicians (STTs) and breath alcohol technicians (BATs) meeting their respective requirements of this subpart are the only people authorized to conduct DOT alcohol tests.

(b) An STT can conduct only alcohol screening tests, but a BAT can conduct alcohol screening and confirmation tests.

(c) As a BAT- or STT-qualified immediate supervisor of a particular employee, you may not act as the STT or BAT when that employee is tested, unless no other STT or BAT is available and DOT agency regulations do not prohibit you from doing so.

§ 40.213 What training requirements must STTs and BATs meet?

To be permitted to act as a BAT or STT in the DOT alcohol testing program, you must meet each of the requirements of this section:

(a) *Basic information.* You must be knowledgeable about the alcohol testing procedures in this part and the current DOT guidance. These documents and information are available from ODAPC (Department of Transportation, 400 7th Street, SW., Room 10403, Washington DC, 20590, 202–366–3784, or on the ODAPC web site, http://www.dot.gov/ost/dapc)).

(b) *Qualification training.* You must receive qualification training meeting the requirements of this paragraph (b).

(1) Qualification training must be in accordance with the DOT Model BAT or STT Course, as applicable. The DOT Model Courses are available from ODAPC (Department of Transportation, 400 7th Street, SW., Room 10403, Washington DC, 20590, 202–366–3784, or on the ODAPC web site, http://www.dot.gov/ost/dapc). The training can also be provided using a course of instruction equivalent to the DOT Model Courses. On request, ODAPC will review BAT and STT instruction courses for equivalency.

(2) Qualification training must include training to proficiency in using the alcohol testing procedures of this part and in the operation of the particular alcohol testing device(s) (*i.e.,* the ASD(s) or EBT(s)) you will be using.

(3) The training must emphasize that you are responsible for maintaining the integrity of the testing process, ensuring the privacy of employees being tested, and avoiding conduct or statements that could be viewed as offensive or inappropriate.

(4) The instructor must be an individual who has demonstrated necessary knowledge, skills, and abilities by regularly conducting DOT alcohol tests as an STT or BAT, as applicable, for a period of at least a year, who has conducted STT or BAT training, as applicable, under this part for a year, or who has successfully completed a ''train the trainer'' course.

(c) *Initial Proficiency Demonstration.* Following your completion of qualification training under paragraph (b) of this section, you must demonstrate proficiency in alcohol testing under this part by completing three consecutive error-free mock tests.

(1) Another person must monitor and evaluate your performance, in person or by a means that provides real-time observation and interaction between the instructor and trainee, and attest in writing that the mock collections are ''error-free.'' This person must be an individual who meets the requirements of paragraph (b)(4) of this section.

(2) These tests must use the alcohol testing devices (*e.g.,* EBT(s) or ASD(s)) that you will use as a BAT or STT.

(3) If you are an STT who will be using an ASD that indicates readings by

changes, contrasts, or other readings in color, you must demonstrate as part of the mock test that you are able to discern changes, contrasts, or readings correctly.

(d) *Schedule for qualification training and initial proficiency demonstration.* The following is the schedule for qualification training and the initial proficiency demonstration you must meet:

(1) If you became a BAT or STT before August 1, 2001, you were required to have met the requirements set forth in paragraphs (b) and (c) of this section, and you do not have to meet them again.

(2) If you become a BAT or STT on or after August 1, 2001, you must meet the requirements of paragraphs (b) and (c) of this section before you begin to perform BAT or STT functions.

(e) *Refresher training.* No less frequently than every five years from the date on which you satisfactorily complete the requirements of paragraphs (b) and (c) of this section, you must complete refresher training that meets all the requirements of paragraphs (b) and (c) of this section.

(f) *Error Correction Training.* If you make a mistake in the alcohol testing process that causes a test to be cancelled (*i.e.,* a fatal or uncorrected flaw), you must undergo error correction training. This training must occur within 30 days of the date you are notified of the error that led to the need for retraining.

(1) Error correction training must be provided and your proficiency documented in writing by a person who meets the requirements of paragraph (b)(4) of this section.

(2) Error correction training is required to cover only the subject matter area(s) in which the error that caused the test to be cancelled occurred.

(3) As part of the error correction training, you must demonstrate your proficiency in the alcohol testing procedures of this part by completing three consecutive error-free mock tests. The mock tests must include one uneventful scenario and two scenarios related to the area(s) in which your error(s) occurred. The person providing the training must monitor and evaluate your performance and attest in writing that the mock tests were error-free.

(g) *Documentation.* You must maintain documentation showing that you currently meet all requirements of this section. You must provide this documentation on request to DOT agency representatives and to employers and C/TPAs who are negotiating to use your services.

(h) *Other persons who may serve as BATs or STTs.* (1) Anyone meeting the requirements of this section to be a BAT may act as an STT, provided that the individual has demonstrated initial proficiency in the operation of the ASD that he or she is using, as provided in paragraph (c) of this section.

(2) Law enforcement officers who have been certified by state or local governments to conduct breath alcohol testing are deemed to be qualified as BATs. They are not required to also complete the training requirements of this section in order to act as BATs. In order for a test conducted by such an officer to be accepted under DOT alcohol testing requirements, the officer must have been certified by a state or local government to use the EBT or ASD that was used for the test.

§ 40.215 What information about the DER do employers have to provide to BATs and STTs?

As an employer, you must provide to the STTs and BATs the name and telephone number of the appropriate DER (and C/TPA, where applicable) to contact about any problems or issues that may arise during the testing process.

§ 40.217 Where is other information on the role of STTs and BATs found in this regulation?

You can find other information on the role and functions of STTs and BATs in the following sections of this part:

§ 40.3—Definitions.
§ 40.223—Responsibility for supervising employees being tested.
§§ 40.225–40.227—Use of the alcohol testing form.
§§ 40.241–40.245—Screening test procedures with ASDs and EBTs.
§§ 40.251–40.255—Confirmation test procedures.
§ 40.261—Refusals to test.
§§ 40.263–40.265—Insufficient saliva or breath.
§ 40.267—Problems requiring cancellation of tests.
§§ 40.269–40.271—Correcting problems in tests.

Subpart K—Testing Sites, Forms, Equipment and Supplies Used in Alcohol Testing

§ 40.221 Where does an alcohol test take place?

(a) A DOT alcohol test must take place at an alcohol testing site meeting the requirements of this section.

(b) If you are operating an alcohol testing site, you must ensure that it meets the security requirements of § 40.223.

(c) If you are operating an alcohol testing site, you must ensure that it provides visual and aural privacy to the employee being tested, sufficient to prevent unauthorized persons from seeing or hearing test results.

(d) If you are operating an alcohol testing site, you must ensure that it has all needed personnel, materials, equipment, and facilities to provide for the collection and analysis of breath and/or saliva samples, and a suitable clean surface for writing.

(e) If an alcohol testing site fully meeting all the visual and aural privacy requirements of paragraph (c) is not readily available, this part allows a reasonable suspicion or post-accident test to be conducted at a site that partially meets these requirements. In this case, the site must afford visual and aural privacy to the employee to the greatest extent practicable.

(f) An alcohol testing site can be in a medical facility, a mobile facility (*e.g.,* a van), a dedicated collection facility, or any other location meeting the requirements of this section.

§ 40.223 What steps must be taken to protect the security of alcohol testing sites?

(a) If you are a BAT, STT, or other person operating an alcohol testing site, you must prevent unauthorized personnel from entering the testing site.

(1) The only people you are to treat as authorized persons are employees being tested, BATs, STTs, and other alcohol testing site workers, DERs, employee representatives authorized by the employer (*e.g.,* on the basis of employer policy or labor-management agreement), and DOT agency representatives.

(2) You must ensure that all persons are under the supervision of a BAT or STT at all times when permitted into the site.

(3) You may remove any person who obstructs, interferes with, or causes unnecessary delay in the testing process.

(b) As the BAT or STT, you must not allow any person other than you, the employee, or a DOT agency representative to actually witness the testing process (see §§ 40.241–40.255).

(c) If you are operating an alcohol testing site, you must ensure that when an EBT or ASD is not being used for testing, you store it in a secure place.

(d) If you are operating an alcohol testing site, you must ensure that no one other than BATs or other employees of the site have access to the site when an EBT is unsecured.

(e) As a BAT or STT, to avoid distraction that could compromise security, you are limited to conducting an alcohol test for only one employee at a time.

(1) When an EBT screening test on an employee indicates an alcohol

concentration of 0.02 or higher, and the same EBT will be used for the confirmation test, you are not allowed to use the EBT for a test on another employee before completing the confirmation test on the first employee.

(2) As a BAT who will conduct both the screening and the confirmation test, you are to complete the entire screening and confirmation process on one employee before starting the screening process on another employee.

(3) You are not allowed to leave the alcohol testing site while the testing process for a given employee is in progress, except to notify a supervisor or contact a DER for assistance in the case an employee or other person who obstructs, interferes with, or unnecessarily delays the testing process.

§ 40.225 What form is used for an alcohol test?

(a) The DOT Alcohol Testing Form (ATF) must be used for every DOT alcohol test. The ATF must be a three-part carbonless manifold form. The ATF is found in Appendix G to this part. You may view this form on the ODAPC web site (http://www.dot.gov/ost/dapc).

(b) As an employer in the DOT alcohol testing program, you are not permitted to modify or revise the ATF except as follows:

(1) You may include other information needed for billing purposes, outside the boundaries of the form.

(2) You may use a ATF directly generated by an EBT which omits the space for affixing a separate printed result to the ATF, provided the EBT prints the result directly on the ATF.

(3) You may use an ATF that has the employer's name, address, and telephone number preprinted. In addition, a C/TPA's name, address, and telephone number may be included, to assist with negative results.

(4) You may use an ATF in which all pages are printed on white paper. The white pages must have either clearly discernible borders in the specified color for each page or designation statements for each copy in the specified color.

(5) As a BAT or STT, you may add, on the ''Remarks'' line of the ATF, the name of the DOT agency under whose authority the test occurred.

(6) As a BAT or STT, you may use a ATF that has your name, address, and telephone number preprinted, but under no circumstances can your signature be preprinted.

(c) As an employer, you may use an equivalent foreign-language version of the ATF approved by ODAPC. You may use such a non-English language form only in a situation where both the employee and BAT/STT understand and can use the form in that language.

§ 40.227 May employers use the ATF for non-DOT tests, or non-DOT forms for DOT tests?

(a) No, as an employer, BAT, or STT, you are prohibited from using the ATF for non-DOT alcohol tests. You are also prohibited from using non-DOT forms for DOT alcohol tests. Doing either subjects you to enforcement action under DOT agency regulations.

(b) If the STT or BAT, either by mistake, or as the only means to conduct a test under difficult circumstances (*e.g.,* post-accident test with insufficient time to obtain the ATF), uses a non-DOT form for a DOT test, the use of a non-DOT form does not, in and of itself, require the employer or service agent to cancel the test. However, in order for the test to be considered valid, a signed statement must be obtained from the STT or BAT in accordance with § 40.271(b) .

§ 40.229 What devices are used to conduct alcohol screening tests?

EBTs and ASDs on the NHTSA conforming products lists (CPL) for evidential and non-evidential devices are the only devices you are allowed to use to conduct alcohol screening tests under this part. An ASD can be used only for screening tests for alcohol, and may not be used for confirmation tests.

§ 40.231 What devices are used to conduct alcohol confirmation tests?

(a) EBTs on the NHTSA CPL for evidential devices that meet the requirements of paragraph (b) of this section are the only devices you may use to conduct alcohol confirmation tests under this part. Note that, among devices on the CPL for EBTs, only those devices listed without an asterisk (*) are authorized for use in confirmation testing in the DOT alcohol testing program.

(b) To conduct a confirmation test, you must use an EBT that has the following capabilities:

(1) Provides a printed triplicate result (or three consecutive identical copies of a result) of each breath test;

(2) Assigns a unique number to each completed test, which the BAT and employee can read before each test and which is printed on each copy of the result;

(3) Prints, on each copy of the result, the manufacturer's name for the device, its serial number, and the time of the test;

(4) Distinguishes alcohol from acetone at the 0.02 alcohol concentration level;

(5) Tests an air blank; and

(6) Performs an external calibration check.

§ 40.233 What are the requirements for proper use and care of EBTs?

(a) As an EBT manufacturer, you must submit, for NHTSA approval, a quality assurance plan (QAP) for your EBT before NHTSA places the EBT on the CPL.

(1) Your QAP must specify the methods used to perform external calibration checks on the EBT, the tolerances within which the EBT is regarded as being in proper calibration, and the intervals at which these checks must be performed. In designating these intervals, your QAP must take into account factors like frequency of use, environmental conditions (*e.g.,* temperature, humidity, altitude) and type of operation (*e.g.,* stationary or mobile).

(2) Your QAP must also specify the inspection, maintenance, and calibration requirements and intervals for the EBT.

(b) As the manufacturer, you must include, with each EBT, instructions for its use and care consistent with the QAP.

(c) As the user of the EBT (*e.g.,* employer, service agent), you must do the following:

(1) You must follow the manufacturer's instructions (see paragraph (b) of this section), including performance of external calibration checks at the intervals the instructions specify.

(2) In conducting external calibration checks, you must use only calibration devices appearing on NHTSA's CPL for ''Calibrating Units for Breath Alcohol Tests.''

(3) If an EBT fails an external check of calibration, you must take the EBT out of service. You may not use the EBT again for DOT alcohol testing until it is repaired and passes an external calibration check.

(4) You must maintain records of the inspection, maintenance, and calibration of EBTs as provided in § 40.333(a)(2) .

(5) You must ensure that inspection, maintenance, and calibration of the EBT are performed by its manufacturer or a maintenance representative certified either by the manufacturer or by a state health agency or other appropriate state agency.

§ 40.235 What are the requirements for proper use and care of ASDs?

(a) As an ASD manufacturer, you must submit, for NHTSA approval, a QAP for your ASD before NHTSA places the ASD on the CPL. Your QAP must

specify the methods used for quality control checks, temperatures at which the ASD must be stored and used, the shelf life of the device, and environmental conditions (*e.g.,* temperature, altitude, humidity) that may affect the ASD's performance.

(b) As a manufacturer, you must include with each ASD instructions for its use and care consistent with the QAP. The instructions must include directions on the proper use of the ASD, and, where applicable the time within which the device must be read, and the manner in which the reading is made.

(c) As the user of the ADS (*e.g.,* employer, STT), you must follow the QAP instructions.

(d) You are not permitted to use an ASD that does not pass the specified quality control checks or that has passed its expiration date.

(e) As an employer, with respect to breath ASDs, you must also follow the device use and care requirements of § 40.233 .

Subpart L—Alcohol Screening Tests

§ 40.241 What are the first steps in any alcohol screening test?

As the BAT or STT you will take the following steps to begin all alcohol screening tests, regardless of the type of testing device you are using:

(a) When a specific time for an employee's test has been scheduled, or the collection site is at the employee's worksite, and the employee does not appear at the collection site at the scheduled time, contact the DER to determine the appropriate interval within which the DER has determined the employee is authorized to arrive. If the employee's arrival is delayed beyond that time, you must notify the DER that the employee has not reported for testing. In a situation where a C/TPA has notified an owner/operator or other individual employee to report for testing and the employee does not appear, the C/TPA must notify the employee that he or she has refused to test.

(b) Ensure that, when the employee enters the alcohol testing site, you begin the alcohol testing process without undue delay. For example, you must not wait because the employee says he or she is not ready or because an authorized employer or employee representative is delayed in arriving.

(1) If the employee is also going to take a DOT drug test, you must, to the greatest extent practicable, ensure that the alcohol test is completed before the urine collection process begins.

(2) If the employee needs medical attention (*e.g.,* an injured employee in an emergency medical facility who is required to have a post-accident test), do not delay this treatment to conduct a test.

(c) Require the employee to provide positive identification. You must see a photo ID issued by the employer (other than in the case of an owner-operator or other self-employer individual) or a Federal, state, or local government (*e.g.,* a driver's license). You may not accept faxes or photocopies of identification. Positive identification by an employer representative (not a co-worker or another employee being tested) is also acceptable. If the employee cannot produce positive identification, you must contact a DER to verify the identity of the employee.

(d) If the employee asks, provide your identification to the employee. Your identification must include your name and your employer's name but is not required to include your picture, address, or telephone number.

(e) Explain the testing procedure to the employee, including showing the employee the instructions on the back of the ATF.

(f) Complete Step 1 of the ATF.

(g) Direct the employee to complete Step 2 on the ATF and sign the certification. If the employee refuses to sign this certification, you must document this refusal on the ''Remarks'' line of the ATF and immediately notify the DER. This is a refusal to test.

§ 40.243 What is the procedure for an alcohol screening test using an EBT or non-evidential breath ASD?

As the BAT or STT, you must take the following steps:

(a) Select, or allow the employee to select, an individually wrapped or sealed mouthpiece from the testing materials.

(b) Open the individually wrapped or sealed mouthpiece in view of the employee and insert it into the device in accordance with the manufacturer's instructions.

(c) Instruct the employee to blow steadily and forcefully into the mouthpiece for at least six seconds or until the device indicates that an adequate amount of breath has been obtained.

(d) Show the employee the displayed test result.

(e) If the device is one that prints the test number, testing device name and serial number, time, and result directly onto the ATF, you must check to ensure that the information has been printed correctly onto the ATF.

(f) If the device is one that prints the test number, testing device name and serial number, time and result, but on a separate printout rather than directly onto the ATF, you must affix the printout of the information to the designated space on the ATF with tamper-evident tape or use a self-adhesive label that is tamper-evident.

(g) If the device is one that does not print the test number, testing device name and serial number, time, and result, or it is a device not being used with a printer, you must record this information in Step 3 of the ATF.

§ 40.245 What is the procedure for an alcohol screening test using a saliva ASD?

As the STT, you must take the following steps:

(a) Check the expiration date on the device and show it to the employee. You may not use the device after its expiration date.

(b) Open an individually wrapped or sealed package containing the device in the presence of the employee.

(c) Offer the employee the opportunity to use the device. If the employee uses it, you must instruct the employee to insert it into his or her mouth and use it in a manner described by the device's manufacturer.

(d) If the employee chooses not to use the device, or in all cases in which a new test is necessary because the device did not activate (see paragraph (g) of this section), you must insert the device into the employee's mouth and gather saliva in the manner described by the device's manufacturer. You must wear single-use examination or similar gloves while doing so and change them following each test.

(e) When the device is removed from the employee's mouth, you must follow the manufacturer's instructions regarding necessary next steps in ensuring that the device has activated.

(f)(1) If you were unable to successfully follow the procedures of paragraphs (c) through (e) of this section (*e.g.,* the device breaks, you drop the device on the floor), you must discard the device and conduct a new test using a new device.

(2) The new device you use must be one that has been under your control or that of the employer before the test.

(3) You must note on the ''Remarks'' line of the ATF the reason for the new test. (Note: You may continue using the same ATF with which you began the test.)

(4) You must offer the employee the choice of using the device or having you use it unless the employee, in the opinion of the STT or BAT, was responsible (*e.g.,* the employee dropped the device) for the new test needing to be conducted.

(5) If you are unable to successfully follow the procedures of paragraphs (c)

through (e) of this section on the new test, you must end the collection and put an explanation on the ''Remarks'' line of the ATF.

(6) You must then direct the employee to take a new test immediately, using an EBT for the screening test.

(g) If you are able to successfully follow the procedures of paragraphs (c)–(e) of this section, but the device does not activate, you must discard the device and conduct a new test, in the same manner as provided in paragraph (f) of this section. In this case, you must place the device into the employee's mouth to collect saliva for the new test.

(h) You must read the result displayed on the device no sooner than the device's manufacturer instructs. In all cases the result displayed must be read within 15 minutes of the test. You must then show the device and its reading to the employee and enter the result on the ATF.

(i) You must never re-use devices, swabs, gloves or other materials used in saliva testing.

(j) You must note the fact that you used a saliva ASD in Step 3 of the ATF.

§ 40.247 What procedures does the BAT or STT follow after a screening test result?

(a) If the test result is an alcohol concentration of less than 0.02, as the BAT or STT, you must do the following:

(1) Sign and date Step 3 of the ATF; and

(2) Transmit the result to the DER in a confidential manner, as provided in § 40.255 .

(b) If the test result is an alcohol concentration of 0.02 or higher, as the BAT or STT, you must direct the employee to take a confirmation test.

(1) If you are the BAT who will conduct the confirmation test, you must then conduct the test using the procedures beginning at § 40.251 .

(2) If you are not the BAT who will conduct the confirmation test, direct the employee to take a confirmation test, sign and date Step 3 of the ATF, and give the employee Copy 2 of the ATF.

(3) If the confirmation test will be performed at a different site from the screening test, you must take the following additional steps:

(i) Advise the employee not to eat, drink, put anything (*e.g.,* cigarette, chewing gum) into his or her mouth, or belch;

(ii) Tell the employee the reason for the waiting period required by § 40.251(a) (*i.e.,* to prevent an accumulation of mouth alcohol from leading to an artificially high reading);

(iii) Explain that following your instructions concerning the waiting period is to the employee's benefit;

(iv) Explain that the confirmation test will be conducted at the end of the waiting period, even if the instructions have not been followed;

(v) Note on the ''Remarks'' line of the ATF that the waiting period instructions were provided;

(vi) Instruct the person accompanying the employee to carry a copy of the ATF to the BAT who will perform the confirmation test; and

(vii) Ensure that you or another BAT, STT, or employer representative observe the employee as he or she is transported to the confirmation testing site. You must direct the employee not to attempt to drive a motor vehicle to the confirmation testing site.

(c) If the screening test is invalid, you must, as the BAT or STT, tell the employee the test is cancelled and note the problem on the ''Remarks'' line of the ATF. If practicable, repeat the testing process (see § 40. 271).

Subpart M—Alcohol Confirmation Tests

§ 40.251 What are the first steps in an alcohol confirmation test?

As the BAT for an alcohol confirmation test, you must follow these steps to begin the confirmation test process:

(a) You must carry out a requirement for a waiting period before the confirmation test, by taking the following steps:

(1) You must ensure that the waiting period lasts at least 15 minutes, starting with the completion of the screening test. After the waiting period has elapsed, you should begin the confirmation test as soon as possible, but not more than 30 minutes after the completion of the screening test.

(i) If the confirmation test is taking place at a different location from the screening test (see § 40.247(b)(3)) the time of transit between sites counts toward the waiting period if the STT or BAT who conducted the screening test provided the waiting period instructions.

(ii) If you cannot verify, through review of the ATF, that waiting period instructions were provided, then you must carry out the waiting period requirement.

(iii) You or another BAT or STT, or an employer representative, must observe the employee during the waiting period.

(2) Concerning the waiting period, you must tell the employee:

(i) Not to eat, drink, put anything (*e.g.,* cigarette, chewing gum) into his or her mouth, or belch;

(ii) The reason for the waiting period (*i.e.,* to prevent an accumulation of mouth alcohol from leading to an artificially high reading);

(iii) That following your instructions concerning the waiting period is to the employee's benefit; and

(iv) That the confirmation test will be conducted at the end of the waiting period, even if the instructions have not been followed.

(3) If you become aware that the employee has not followed the instructions, you must note this on the ''Remarks'' line of the ATF.

(b) If you did not conduct the screening test for the employee, you must require positive identification of the employee, explain the confirmation procedures, and use a new ATF. You must note on the ''Remarks'' line of the ATF that a different BAT or STT conducted the screening test.

(c) Complete Step 1 of the ATF.

(d) Direct the employee to complete Step 2 on the ATF and sign the certification. If the employee refuses to sign this certification, you must document this refusal on the ''Remarks'' line of the ATF and immediately notify the DER. This is a refusal to test.

(e) Even if more than 30 minutes have passed since the screening test result was obtained, you must begin the confirmation test procedures in § 40.253, not another screening test.

(f) You must note on the ''Remarks'' line of the ATF the time that elapsed between the two events, and if the confirmation test could not begin within 30 minutes of the screening test, the reason why.

(g) Beginning the confirmation test procedures after the 30 minutes have elapsed does not invalidate the screening or confirmation tests, but it may constitute a regulatory violation subject to DOT agency sanction.

§ 40.253 What are the procedures for conducting an alcohol confirmation test?

As the BAT conducting an alcohol confirmation test, you must follow these steps in order to complete the confirmation test process:

(a) In the presence of the employee, you must conduct an air blank on the EBT you are using before beginning the confirmation test and show the reading to the employee.

(1) If the reading is 0.00, the test may proceed. If the reading is greater than 0.00, you must conduct another air blank.

(2) If the reading on the second air blank is 0.00, the test may proceed. If the reading is greater than 0.00, you must take the EBT out of service.

(3) If you take an EBT out of service for this reason, no one may use it for testing until the EBT is found to be

within tolerance limits on an external check of calibration.

(4) You must proceed with the test of the employee using another EBT, if one is available.

(b) You must open a new individually wrapped or sealed mouthpiece in view of the employee and insert it into the device in accordance with the manufacturer's instructions.

(c) You must ensure that you and the employee read the sequential test number displayed on the EBT.

(d) You must instruct the employee to blow steadily and forcefully into the mouthpiece for at least six seconds or until the device indicates that an adequate amount of breath has been obtained.

(e) You must show the employee the result displayed on the EBT.

(f) You must show the employee the result and unique test number that the EBT prints out either directly onto the ATF or onto a separate printout.

(g) If the EBT provides a separate printout of the result, you must attach the printout to the designated space on the ATF with tamper-evident tape, or use a self-adhesive label that is tamper-evident.

§ 40.255 What happens next after the alcohol confirmation test result?

(a) After the EBT has printed the result of an alcohol confirmation test, you must, as the BAT, take the following additional steps:

(1) Sign and date Step 3 of the ATF.

(2) If the alcohol confirmation test result is lower than 0.02, nothing further is required of the employee. As the BAT, you must sign and date Step 3 of the ATF.

(3) If the alcohol confirmation test result is 0.02 or higher, direct the employee to sign and date Step 4 of the ATF. If the employee does not do so, you must note this on the ''Remarks'' line of the ATF. However, this is not considered a refusal to test.

(4) If the test is invalid, tell the employee the test is cancelled and note the problem on the ''Remarks'' line of the ATF. If practicable, conduct a re-test. (see § 40.271).

(5) Immediately transmit the result directly to the DER in a confidential manner.

(i) You may transmit the results using Copy 1 of the ATF, in person, by telephone, or by electronic means. In any case, you must immediately notify the DER of any result of 0.02 or greater by any means (*e.g.,* telephone or secure fax machine) that ensures the result is immediately received by the DER. You must not transmit these results through C/TPAs or other service agents.

(ii) If you do not make the initial transmission in writing, you must follow up the initial transmission with Copy 1 of the ATF.

(b) As an employer, you must take the following steps with respect to the receipt and storage of alcohol test result information:

(1) If you receive any test results that are not in writing (*e.g.,* by telephone or electronic means), you must establish a mechanism to establish the identity of the BAT sending you the results.

(2) You must store all test result information in a way that protects confidentiality.

Subpart N—Problems in Alcohol Testing

§ 40.261 What is a refusal to take an alcohol test, and what are the consequences?

(a) As an employee, you are considered to have refused to take an alcohol test if you:

(1) Fail to appear for any test within a reasonable time, as determined by the employer, after being directed to do so by the employer. This includes the failure of an employee (including an owner-operator) to appear for a test when called by C/TPA (see § 40.241(b)(1));

(2) Fail to remain at the testing site until the testing process is complete;

(3) Fail to attempt to provide a saliva or breath specimen, as applicable, for any test required by this part or DOT agency regulations;

(4) Fail to provide a sufficient breath specimen, and the physician has determined, through a required medical evaluation, that there was no adequate medical explanation for the failure (see § 40.265(c));

(5) Fail to undergo a medical examination or evaluation, as directed by the employer as part of the insufficient breath procedures outlined at § 40.265(c);

(6) Fail to sign the certification at Step 2 of the ATF (see § 40.241(b)(7)); or

(7) Fail to cooperate with any part of the testing process.

(b) As an employee, if you refuse to take an alcohol test, you incur the same consequences specified under DOT agency regulations for a violation of those DOT agency regulations.

(c) As a BAT or an STT, or as the physician evaluating a ''shy lung'' situation, when an employee refuses to test as provided in paragraph (a) of this section, you must terminate the portion of the testing process in which you are involved, document the refusal on the ATF (or in a separate document which you cause to be attached to the form), immediately notify the DER by any means (*e.g.,* telephone or secure fax machine) that ensures the refusal notification is immediately received. You must make this notification directly to the DER (not using a C/TPA as an intermediary).

(d) As an employee, when you refuse to take a non-DOT test or to sign a non-DOT form, you have not refused to take a DOT test. There are no consequences under DOT agency regulations for such a refusal.

§ 40.263 What happens when an employee is unable to provide a sufficient amount of saliva for an alcohol screening test?

(a) As the STT, you must take the following steps if an employee is unable to provide sufficient saliva to complete a test on a saliva screening device (*e.g.*, the employee does not provide sufficient saliva to activate the device).

(1) You must conduct a new screening test using a new screening device.

(2) If the employee refuses to make the attempt to complete the new test, you must discontinue testing, note the fact on the ''Remarks'' line of the ATF, and immediately notify the DER. This is a refusal to test.

(3) If the employee has not provided a sufficient amount of saliva to complete the new test, you must note the fact on the ''Remarks'' line of the ATF and immediately notify the DER.

(b) As the DER, when the STT informs you that the employee has not provided a sufficient amount of saliva (see paragraph (a)(3) of this section), you must immediately arrange to administer an alcohol test to the employee using an EBT or other breath testing device.

§ 40.265 What happens when an employee is unable to provide a sufficient amount of breath for an alcohol test?

(a) If an employee does not provide a sufficient amount of breath to permit a valid breath test, you must take the steps listed in this section.

(b) As the BAT or STT, you must instruct the employee to attempt again to provide a sufficient amount of breath and about the proper way to do so.

(1) If the employee refuses to make the attempt, you must discontinue the test, note the fact on the ''Remarks'' line of the ATF, and immediately notify the DER. This is a refusal to test.

(2) If the employee again attempts and fails to provide a sufficient amount of breath, you may provide another opportunity to the employee to do so if you believe that there is a strong likelihood that it could result in providing a sufficient amount of breath.

(3) When the employee's attempts under paragraph (b)(2) of this section

have failed to produce a sufficient amount of breath, you must note the fact on the ''Remarks'' line of the ATF and immediately notify the DER.

(4) If you are using an EBT that has the capability of operating manually, you may attempt to conduct the test in manual mode.

(5) If you are qualified to use a saliva ASD and you are in the screening test stage, you may change to a saliva ASD only to complete the screening test.

(c) As the employer, when the BAT or STT informs you that the employee has not provided a sufficient amount of breath, you must direct the employee to obtain, within five days, an evaluation from a licensed physician who is acceptable to you and who has expertise in the medical issues raised by the employee's failure to provide a sufficient specimen.

(1) You are required to provide the physician who will conduct the evaluation with the following information and instructions:

(i) That the employee was required to take a DOT breath alcohol test, but was unable to provide a sufficient amount of breath to complete the test;

(ii) The consequences of the appropriate DOT agency regulation for refusing to take the required alcohol test;

(iii) That the physician must provide you with a signed statement of his or her conclusions; and

(iv) That the physician, in his or her reasonable medical judgment, must base those conclusions on one of the following determinations:

(A) A medical condition has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of breath. The physician must not include in the signed statement detailed information on the employee's medical condition. In this case, the test is cancelled.

(B) There is not an adequate basis for determining that a medical condition has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of breath. This constitutes a refusal to test.

(C) For purposes of paragraphs (c)(1)(iv)(A) and (B) of this section, a medical condition includes an ascertainable physiological condition (*e.g.*, a respiratory system dysfunction) or a medically documented pre-existing psychological disorder, but does not include unsupported assertions of ''situational anxiety'' or hyperventilation.

(2) As the physician making the evaluation, after making your determination, you must provide a written statement of your conclusions and the basis for them to the DER directly (and not through a C/TPA acting as an itermediary). You must not include in this statement detailed information on the employee's medical condition beyond what is necessary to explain your conclusion.

(3) Upon receipt of the report from the examining physician, as the DER you must immediately inform the employee and take appropriate action based upon your DOT agency regulations.

§ 40.267 What problems always cause an alcohol test to be cancelled?

As an employer, a BAT, or an STT, you must cancel an alcohol test if any of the following problems occur. These are ''fatal flaws.'' You must inform the DER that the test was cancelled and must be treated as if the test never occurred. These problems are:

(a) In the case of a screening test conducted on a saliva ASD:

(1) The STT reads the result either sooner than or later than the time allotted by the manufacturer (see § 40.245(h));

(2) The device does not activate (see § 40.245(g)); or

(3) The device is used for a test after the expiration date printed on its package (see § 40.245(a)).

(b) In the case of a screening or confirmation test conducted on an EBT, the sequential test number or alcohol concentration displayed on the EBT is not the same as the sequential test number or alcohol concentration on the printed result (see § 40.253(c), (e) and (f)).

(c) In the case of a confirmation test:

(1) The BAT conducts the confirmation test before the end of the minimum 15-minute waiting period (see § 40.251(a)(1));

(2) The BAT does not conduct an air blank before the confirmation test (see § 40.253(a));

(3) There is not a 0.00 result on the air blank conducted before the confirmation test (see § 40.253(a)(1) and (2));

(4) The EBT does not print the result (see § 40.253(f)); or

(5) The next external calibration check of the EBT produces a result that differs by more than the tolerance stated in the QAP from the known value of the test standard. In this case, every result of 0.02 or above obtained on the EBT since the last valid external calibration check is cancelled (see § 40.233(a)(1) and (d)).

§ 40.269 What problems cause an alcohol test to be cancelled unless they are corrected?

As a BAT or STT, or employer, you must cancel an alcohol test if any of the following problems occur, unless they are corrected. These are ''correctable flaws.'' These problems are:

(a) The BAT or STT does not sign the ATF (see § § 40.247(a)(1) and 40.255(a)(1)).

(b) The BAT or STT fails to note on the ''Remarks'' line of the ATF that the employee has not signed the ATF after the result is obtained (see § 40.255(a)(2)).

(c) The BAT or STT uses a non-DOT form for the test (see § 40.225(a)).

§ 40.271 How are alcohol testing problems corrected?

(a) As a BAT or STT, you have the responsibility of trying to complete successfully an alcohol test for each employee.

(1) If, during or shortly after the testing process, you become aware of any event that will cause the test to be cancelled (see § 40.267), you must try to correct the problem promptly, if practicable. You may repeat the testing process as part of this effort.

(2) If repeating the testing process is necessary, you must begin a new test as soon as possible. You must use a new ATF, a new sequential test number, and, if needed, a new ASD and/or a new EBT. It is permissible to use additional technical capabilities of the EBT (*e.g.*, manual operation) if you have been trained to do so in accordance with § 40.213(c) .

(3) If repeating the testing process is necessary, you are not limited in the number of attempts to complete the test, provided that the employee is making a good faith effort to comply with the testing process.

(4) If another testing device is not available for the new test at the testing site, you must immediately notify the DER and advise the DER that the test could not be completed. As the DER who receives this information, you must make all reasonable efforts to ensure that the test is conducted at another testing site as soon as possible.

(b) If, as an STT, BAT, employer or other service agent administering the testing process, you become aware of a ''correctable flaw'' (see § 40.269) that has not already been corrected, you must take all practicable action to correct the problem so that the test is not cancelled.

(1) If the problem resulted from the omission of required information, you must, as the person responsible for providing that information, supply in writing the missing information and a signed statement that it is true and accurate. For example, suppose you are a BAT and you forgot to make a notation on the ''Remarks'' line of the ATF that